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Proposed Registration Decision

Dimethenamid-P

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Overview

Proposed Registration Decision for Dimethenamid-P

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Dimethenamid-P Technical Herbicide and Frontier Max Herbicide, containing the technical grade active ingredient dimethenamid-P, to control certain annual grassy weeds as well as redroot pigweed, eastern black nightshade and yellow nutsedge in corn, soybeans, dry common beans, dry bulb onions, transplanted cabbage, peanuts and non-bearing grape vines.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Dimethenamid-P Technical Herbicide and Frontier Max Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on dimethenamid-P, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on dimethenamid-P, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Dimethenamid-P?

Dimethenamid-P is a herbicide which inhibits protein and flavonoid biosynthesis. These biochemical effects result in inhibition of cell division and tissue differentiation in susceptible plant species, with death of these plant species occurring prior to or soon after emergence from the soil.

Frontier Max Herbicide contains dimethenamid-P and can be applied as a pre-plant incorporated, pre-plant, pre-emergence or post-emergence treatment to control the labelled annual grassy weeds plus redroot pigweed, Eastern black nightshade and yellow nutsedge in a variety of crops.

Health Considerations

Can Approved Uses of Dimethenamid-P Affect Human Health?

Dimethenamid-P is unlikely to affect your health when used according to label directions.

Potential exposure to dimethenamid-P may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when dimethenamid-P products are used according to label directions.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The technical grade active ingredient dimethenamid-P was highly toxic by the oral route in animals. It also tested positive for dermal sensitization. Consequently, the statements "DANGER–POISON" and "Potential Skin Sensitizer" are required on the label.

The end use product Frontier Max Herbicide is of moderate toxicity when given as a single oral dose to rats, and is moderately irritating to the eye of rabbits. It also tested positive for dermal sensitization. Consequently, the statements "WARNING–POISON", "Warning–Eye Irritant" and "Potential Skin Sensitizer" are required on the label.

Dimethenamid-P did not cause cancer in animals and was not genotoxic. There was also no indication that dimethenamid-P caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of dimethenamid-P over longer periods of time were decreased body-weight gain and increased liver weights with associated cellular and clinical chemistry effects.

When dimethenamid-P was given to pregnant animals, no effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is not more sensitive to dimethenamid-P than the adult animal. Because of this observation, extra protective measures beyond those that are normally applied were not required.

The risk assessment protects against adverse effects from dimethenamid-P by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As the metabolism of dimethenamid-P and dimethenamid (racemic mixture), were demonstrated to be the same, all the residue data generated with dimethenamid is bridged to dimethenamid-P. Aggregate dietary intake estimates (food plus water) revealed that children 1–2 years old, the subpopulation which would ingest the most dimethenamid and/or dimethenamid-P relative to body weight, is expected to be exposed to 10.1% or less of the acceptable daily intake. Based on these estimates, the chronic dietary risk from dimethenamid and dimethenamid-P is not of concern for all segments of the population. Dimethenamid is not carcinogenic. Therefore, a chronic cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects at dose levels relevant to dietary consumption. Consequently, a single dose of dimethenamid or dimethenamid-P is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide

MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using dimethenamid on field and sweet corn, soybeans, dry common beans, dry bulb onions, transplanted cabbage and peanuts were acceptable. The MRLs established to cover residues of dimethenamid will be used to cover residues of dimethenamid-P.

Occupational Health Risks From Handling Frontier Max Herbicide

Occupational health risks are not of concern when Frontier Max Herbicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply as well as field workers who re-enter freshly treated fields can come into direct contact with Frontier Max Herbicide residues on the skin. The label will specify that workers handling Frontier Max Herbicide must wear a long-sleeved shirt, long pants, coveralls and chemical resistant gloves and shoes plus socks during mixing, loading, application, clean-up and repair. In addition, the label will specify that goggles or a face shield must be worn during mixing/loading.

The label also specifies that workers must not enter treated fields for 24 hours. Taking into consideration these label requirements, risks to agricultural workers are not of concern.

Risks in Residential and Other Non-Occupational Environments

For bystanders, the exposure is expected to be much less than that of field workers and is considered negligible when the product is used according to label directions. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Dimethenamid-P Is Intr[illegible]ced Into the Environment?

When used according to label directions, Frontier Max Herbicide does not pose an unacceptable risk to the environment. However, precautionary measures are required to mitigate the potential risks of dimethenamid-P to terrestrial and aquatic plants and small wild mammals.

Dimethenamid-P enters the environment when used as a herbicide for various crops. In the terrestrial environment, dimethenamid-P is non-persistent in aerobic soil and moderately persistent in anaerobic soil. It has a potential for leaching in soils. Biotransformation is expected to be the main route of dissipation in soil for dimethenamid-P.

Dimethenamid-P can enter the aquatic environment through spray drift and run-off from the site of application. In aquatic systems, dimethenamid-P is slightly persistent under aerobic and anaerobic conditions. Biotransformation, rather than hydrolysis and photolysis, is expected to be the main route of dissipation for dimethenamid-P in aquatic systems. Dimethenamid-P is very soluble in water. Based on the environmental fate characteristics, limited run-off of the dimethenamid-P and transformation products is expected. Monitoring data using dimethenamid as a surrogate indicate that dimethenamid-P can be found in surface water sources.

At the maximum application rate of 930 g a.i./ha, a risk assessment identified the potential risks of dimethenamid-P to terrestrial and aquatic plants and mammalian herbivores, for which further mitigation measures are required.

Value Considerations

What Is the Value of Frontier Max Herbicide?

Frontier Max Herbicide controls specific grassy weeds and the broadleaf weeds, redroot pigweed, Eastern black nightshade and yellow nutsedge in a variety of crops

Frontier Max Herbicide can be applied as a pre-plant incorporated, pre-plant, or pre-emergence treatment in field corn, sweet corn, seed corn, soybeans, dry common beans, transplanted cabbage and peanuts; as an early post-emergence treatment in field corn; and can also be directly applied under established first year and second year non-bearing grape vines. A single application of Frontier Max Herbicide at 756–963 mL/hectare (544–693 g a.i./ha) provides control of the labelled annual grassy weeds plus redroot pigweed, Eastern black nightshade and yellow nutsedge. The required application rate for weed control is determined by the application timing, soil texture and soil organic matter content. Medium and fine textured soils with higher organic matter content require higher application rates while coarse textured soils with lower organic matter content require lower application rates. Frontier Max Herbicide at 1.29L/hectare (930 g a.i./ha) can be applied at the loop stage of dry bulb onions grown on muck soils for suppression of yellow nutsedge.

Frontier Herbicide (Reg. No. 23462), which is comprised of the racemic mixture of dimethenamid (45:55 of r- and s-stereoisomers), was cited as a precedent product for Frontier Max Herbicide. Herbicidal activity has been found to be attributed mainly to s-isomer of dimethenamid (i.e. dimethenamid-P) which is the active ingredient of Frontier Max Herbicide. Frontier Max Herbicide provides the same efficacy and crop tolerance as Frontier Herbicide, but will allow for a 45% reduction in the total amount of total dimethenamid applied to field crops as compared to the currently registered racemic mixture of Frontier Herbicide. This results in a reduced herbicidal load on the environment and reduced worker exposure.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Frontier Max Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

- Workers handling Frontier Max Herbicide must wear a long-sleeved shirt, long pants, coveralls and chemical resistant gloves and shoes plus socks during mixing, loading, application, clean-up and repair. In addition, goggles or face shield must be worn during mixing/loading. The label also specifies that workers must not enter treated fields for 24 hours. Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Environment

- Precautionary label statements are required as a result of the environmental risk assessment.
- A buffer zone of 3 m is calculated for the use of Frontier Max Herbicide for protection of terrestrial plants.
- A buffer zone of 1 m is calculated for the use of Frontier Max Herbicide for protection of aquatic habitats.
- A label statement of "Toxic to aquatic organisms, non-target terrestrial plants and small wild mammals" is required to avoid the potential risks of dimethenamid-P to these organisms.

Next Steps

Before making a final registration decision on dimethenamid-P, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

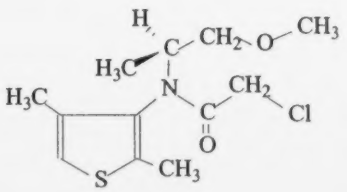
When the PMRA makes its registration decision, it will publish a Registration Decision on dimethenamid-P (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Dimethenamid-P

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Dimethenamid-P
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(S)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-[(1S)-2-methoxy-1-methylethylacetamide
2. Chemical Abstracts Service (CAS)	2-chloro-N-(2,4-dimethyl-3-thienyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide
CAS number	163515-14-8
Molecular formula	$C_{12}H_{18}ClNO_2S$
Molecular weight	275.79
Structural formula	

Purity of the active ingredient 92.9%

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Dimethenamid-P Technical

Property	Result
Colour and physical state	Dark brown liquid
Odour	Strong unpleasant musty odour
Melting range	Not applicable
Boiling point or range	122.6°C at 0.07 mmHg (9.3 Pa)

Property	Result
Density at 20°C	1.194 g/mL
Vapour pressure at 20°C	$2.61 \pm 0.97 \times 10^{-5}$ mmHg
Henry's law constant at 25°C	$1/H = 5.19 \times 10^{6}$
Ultraviolet (UV)–visible spectrum	λ_{max} = 236 nm, no absorption from 300 to 750 nm
Solubility in water at 25°C	1449 ± 17 mg/L
Solubility in organic solvents at 25°C (g/100 mL)	Solvent Solubility Hexane 24.8 soluble at all proportions in tetrahydrofuran, isopropyl alcohol, acetone, acetonitrile, dimethyl sulfoxide, dichloromethane, toluene and n-octanol
n-Octanol-water partition coefficient (K_{OW})	$K_{ow} = 77.6 \pm 17.0$ at 24°C ($\log K_{ow} = 1.89 \pm 0.10$)
Dissociation constant (pK_a)	Not applicable
Stability (temperature, metal)	Stable at 54°C for 14 days and in the presence of iron, copper and aluminum powders over 28 days.

End-Use Product—Frontier Max Herbicide

Property	Result
Colour	Brown
Odour	Aromatic
Physical state	Liquid
Formulation type	Emulsifiable concentrate
Guarantee	720 g/L
Container material and description	10 L fluorinated high density polyethylene containers; 55 and 1000 L bulk totes made of polyethylene linear low plastic
Density at 20°C	1.13 g/mL
pH of 1% dispersion in water	3.1
Oxidizing or reducing action	A moderate reductant, not an oxidant
Storage stability	Stable for two years under commercial storage conditions

Property	Result
Corrosion characteristics	No corrosion to the HDPE containers for two years at commercial storage conditions
Explodability	Not explosive

1.3 Directions for Use

Frontier Max Herbicide is a herbicide that can be applied as a pre-plant incorporated, pre-plant or pre-emergence treatment in field corn, sweet corn, seed corn, soybeans, dry common beans, dry bulb onions, transplanted cabbage and peanuts; as an early post-emergence treatment in field corn; and can also be directly applied under established first year and second year non-bearing grape vines. A single application of Frontier Max Herbicide at 756–963 mL/hectare (544–693 g a.i./ha) provides effective control of annual grassy weeds plus redroot pigweed, eastern black nightshade and yellow nutsedge (Table 1.3.1). The application rate specifically for suppression of yellow nutsedge in dry onions at the loop stage grown on muck soil is 1.29 L/ha (930 g a.i./ha).

The required application rate for effective weed control is determined by the application timing, soil texture and soil organic matter content (Table 1.3.2). Frontier Max Herbicide may only be applied once per season.

Table 1.3.1 Weed Control Claims for Frontier Max Herbicide

Foxtail (green, yellow and giant)	Fall panicum
Crabgrass (smooth and large)	Redroot pigweed*
Old witchgrass	Eastern black nightshade**
Barnyard grass	Yellow nutsedge***

*Pre-plant incorporated (860–963 mL/ha) or pre-emergence (963 mL/ha) only;
**Pre-plant incorporated or pre-emergence (963 mL/ha) only;
***Pre-plant incorporated only (963 mL/ha. Lower rates provide suppression only).

Table 1.3.2 The Rates of Frontier Max Herbicide for Pre-Emergence and Post-Emergence Application Timings

Soil Type	Application Rate		
	< 3% Organic Matter	3–6% Organic Matter	7–10% Organic Matter
Coarse Textured Soils	756 mL/ha (544 g a.i./ha)	756 mL/ha (544 g a.i./ha)	860 mL/ha (619 g a.i./ha)
Medium Textured Soils	756 mL/ha (544 g a.i./ha)	860 mL/ha (619 g a.i./ha)	963 mL/ha (693 g a.i./ha)
Fine Textured Soils	756 mL/ha (544 g a.i./ha)	860 mL/ha (619 g a.i./ha)	963 mL/ha (693 g a.i./ha)

The application rate for pre-plant incorporated treatment is 860-963 mL/ha (619-693 g a.i./ha). Medium and fine textured soils with higher organic matter content require higher application rates while coarse textured soils with lower organic matter content require lower application rates.

Frontier Max Herbicide may be tank mixed with other broadleaf herbicides for broad spectrum weed control in corn and soybean (Table 1.3.3).

Table 1.3.3 Tank Mix Partners for Frontier Max Herbicide

Crops	Timing	Tank Mix Partners (Rate Per Hectare)
Corn (conservation tillage systems)	Pre-plant	Atrazine (0.99–1.53 kg a.i.) or Roundup Original (2.5 L) or Roundup Original + Banvel II Herbicide (2.5 L + 1.25 L) or Roundup Original + Marksman Herbicide (2.5 L + 4.5 L) or Roundup Original + atrazine (2.5 L + 0.99-1.53 kg a.i.)
	Pre-emergence	Banvel II Herbicide (1.25 L) or Marksman Herbicide (4.5 L) or Atrazine (0.99–1.53 kg a.i.) or Roundup Original (2.5 L) or Roundup Original + Banvel II Herbicide (2.5 L + 1.25 L) or Roundup Original + Marksman Herbicide (2.5 L + 4.5 L) or Roundup Original + atrazine (2.5 L + 0.99-1.53 kg a.i.)
Field corn	Pre-plant incorporated	Atrazine (0.99–1.53 kg a.i.)
	Pre-emergence	Atrazine (0.99–1.53 kg a.i.) or Banvel II Herbicide (1.25 L) or Marksman Herbicide (4.5 L)
	Early post-emergence	Atrazine (0.99–1.53 kg a.i.) or Banvel II Herbicide (1.25 L) or Marksman Herbicide (3.7-4.5 L) or Impact + atrazine (37 mL + 500 g a.i.)
Soybeans (conservation tillage systems)	Pre-plant or after seeding but before crop emergence	Roundup Original (2.5 L)
Soybeans	Pre-emergence	Pursuit Herbicide (312–420 mL)

1.4 Mode of Action

Dimethenamid-P is a Group 15 (chloroacetamide) herbicide and inhibits protein and flavonoid biosynthesis and affects isoprenoid biosynthesis. It is postulated that it inhibits the synthesis of coenzyme A conjugates and affects other reactions involving thiol (SH) groups. These biochemical effects result in inhibition of cell division and tissue differentiation in susceptible plant species, with death occurring prior to or soon after emergence from the soil. The primary site of absorption and action on broadleaf species are the roots. The primary site of absorption and action on grass species is the emerging shoot. The acetamides are not readily translocated in plants, so herbicide placement and availability is important.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Compound Dimethenamid-P Technical Herbicide have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

The analytical methods for dimethenamid (racemic mixture) are considered acceptable for the analysis of residues of dimethenamid-P (resolved S-isomer) in plant matrices as the existing methods for dimethenamid cannot separate the enantiomers. Gas chromatography methods with either a thermionic nitrogen specific detector (GC-TSD) or a mass selective detector (GC-MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant matrices. Adequate extraction efficiencies were demonstrated using radiolabeled corn and soybean matrices analyzed with the enforcement method. The enforcement method was successfully validated. Analytical methods for the analysis of dimethenamid residues in livestock matrices were not required as there is no expectation of quantifiable residues in meat, milk and eggs.

For the environmental assessment, gas chromatography (GC) and High-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (78–104%) were obtained in plant and fish matrices and environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

A detailed review of the toxicological database for dimethenamid-P was conducted. The studies submitted included six acute toxicity studies, an in vitro metabolism study, a 90-day toxicity study in rats, a developmental toxicity study and eight genotoxicity studies. The purpose of these studies was to show toxicological equivalency of dimethenamid-P, consisting of the s-isomer, to the currently registered racemic mixture, dimethenamid. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate (when combined with the racemic dimethenamid database) to define the majority of the toxic effects that may result from exposure to this chemical pest control product. The studies submitted for dimethenamid-P showed a strong correlation in terms of toxicity to racemic dimethenamid. The s-isomer, dimethenamid-P, is therefore considered toxicologically equivalent to the racemic dimethenamid.

The technical grade active ingredient dimethenamid-P was highly toxic by the oral route in animals. It also tested positive for dermal sensitization.

The end use product Frontier Max Herbicide is of moderate toxicity when given as a single oral dose to rats, and is moderately irritating to the skin of rabbits. It also tested positive for dermal sensitization.

Following a single oral low or high dose of radiolabeled dimethenamid, absorption was slow with peak blood levels at 48 hours steady through 168 hours. There was no saturation of absorption. Intravenous dosing resulted in constant blood levels throughout the study that were twice as high as the levels resulting from oral dosing. Highest levels were observed in the spleen and in blood. The test substance binds to blood cells, causing a plateau in blood concentrations over time. Following low dose administration of radiolabeled dimethenamid, peak urine excretion was reached at 48 hours and remained relatively constant for 168 hours. The peak was only reached at 72 hours following the high dose. There was a sex difference in terms of excretion with females excreting more radioactivity through the urine, especially at low doses. Bile cannulated rats excreted over 75% of the administered dose through the bile, indicating significant enterohepatic circulation.

Dimethenamid was extensively metabolized in the rat. Sixty-three metabolites were isolated in feces and 48 were isolated in urine and bile. Only 26 metabolites, accounting for 38.5% of the administered dose, were identified. Only 1.5% of recovered radioactivity was the parent compound.

A comparative study was performed in vitro (rat liver slices) to confirm that both the racemic mixture and dimethenamid-P isomer produce the same metabolites. The two compounds were found to produce the same metabolites, though there was some variation in the relative quantities, especially M33 (23.0% in racemate, 15.7% s-isomer) and M35 (15.6% racemate, 20.3% s-isomer).

A short-term dermal study showed some skin irritation after repeated applications of dimethenamid to the shaved skin of rabbits. There were no adverse systemic effects at any dose level.

In subchronic and chronic toxicity studies, dimethenamid produced specific target organ toxicity in the liver of all test species. This toxicity included increased weight, liver cell enlargement and clinical chemistry alterations. The other significant finding that occurred repeatedly was decreased body-weight gain. Following two years of dosing, rats also exhibited hyperplasia in the parathyroid gland and the bile duct. Dimethenamid was not considered oncogenic in either rats or mice. Longer duration dosing increased the degree of toxicity observed (same effects at lower dose levels), however, there were few novel observations following chronic dosing. The dimethenamid-P isomer and the racemic mixture were separately tested in ninety day oral rat studies and showed similar toxicity.

No evidence of mutagenic potential of dimethenamid was observed in vitro with the Ames bacterial gene mutation test. There was one positive result and two negative results from three separate laboratories in unscheduled DNA synthesis assays with rat hepatocytes. Negative results were obtained in an in vitro clastogenicity study using Chinese hamster ovary cells, an in vivo micronuclei assay using mice and a transformation of Balb/3T3 cells test. On the whole, based on the data presented, dimethenamid was not considered to be genotoxic.

In Ames bacterial gene mutation tests with the isomer dimethenamid-P, one positive result was obtained in TA 100 cells without metabolic activation; however, three other similar studies from independent laboratories were negative. Negative results were obtained in Chinese hamster ovary cell assays for gene mutations and chromosome aberrations in vitro, an unscheduled DNA synthesis assay with rat hepatocytes and an in vivo micronucleus study with mice. As with racemic dimethenamid, dimethenamid-P was not considered to be genotoxic.

There was no evidence of increased susceptibility of the young in the oral rat and rabbit developmental toxicity studies using dimethenamid or in the oral rat developmental toxicity study using dimethenamid-P. With dimethenamid, maternal rats showed excess salivation, decreased body-weight gain and increased relative liver weight at the lowest observed adverse effect level (LOAEL), while fetuses exhibited no adverse effects. With dimethenamid-P, the maternal rats only exhibited decreased body-weight gain during dosing and decreased food consumption at the maternal LOAEL (the mid dose), though increased liver weights, salivation and other clinical signs were evident at the high dose. The litters showed an increase in cervical ribs that was just outside of the historical control range and this was the basis for the chosen developmental LOAEL (the highest dose tested). Rabbit dams exhibited decreased body weight and food consumption at the highest dose tested of dimethenamid, while the fetuses showed no direct adverse effects at any dose level. Two dams in the high dose group had abortions near the end of gestation following several days without eating.

In a two-generation reproductive toxicity study with dimethenamid, the parental males showed a decrease in body weight, body-weight gain and food consumption at the highest dose tested. There were no treatment related adverse effects in the parental females. The offspring showed a

decrease in body weight and body-weight gain during lactation at the highest dose tested. There was no evidence of reproductive toxicity.

There was no evidence of neurotoxicity in either racemic dimethenamid or dimethenamid-P.

Results of the acute and chronic tests conducted on laboratory animals with dimethenamid-P Technical Herbicide and its associated end-use product Frontier Max Herbicide, along with the toxicology endpoints for use in the human health risk assessment are summarized in Tables 2, 3 and 4 of Appendix I.

3.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around residential areas or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account completeness of the data with respect to the exposure of, and toxicity to infants and children and potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database, extensive data were available on dimethenamid-P and racemic dimethenamid. The data available included prenatal developmental toxicity studies in rats and rabbits and a two generation reproduction study in rats for racemic dimethenamid and a prenatal developmental toxicity study in rats for dimethenamid-P.

In terms of pre- and post-natal toxicity, there is no evidence of sensitivity of either rat or rabbit fetuses or pups compared to the adult animals via the oral route. Following exposure to either racemic dimethenamid or dimethenamid-P in developmental toxicity studies at the maternal LOAEL, rat fetuses exhibited no adverse effects. Similarly, rabbit fetuses were free of adverse effects at doses toxic to the dams in the developmental toxicity study. Two dams in the high dose group had abortions near the end of gestation following several days without eating.

In a two-generation reproductive toxicity study with dimethenamid in rats, the offspring showed decreased body weight and body-weight gain during lactation. There was no evidence of maternal or reproductive toxicity.

The database for dimethenamid-P, when combined with the available data for racemic dimethenamid, was considered complete. There were no pre or post natal concerns that required consideration in the establishment of the *Pest Control Products Act* factor. As such, a reduction in the *Pest Control Products Act* factor to onefold was warranted.

3.2 Determination of Acute Reference Dose

An acute reference dose was not established as there were no acute endpoints of concern.

3.3 Determination of Acceptable Daily Intake

The recommended acceptable daily intake (ADI) for dimethenamid-P is equivalent to that for racemic dimethenamid, 0.05 mg/kg bw/day, based on the calculation shown below. The rat carcinogenicity study was considered to be the most relevant study for establishment of the ADI. The NOAEL was 5.1 mg/kg bw/day, based on increased parathyroid gland hyperplasia in males and bile duct hyperplasia in females which occurred at 36 mg/kg bw/day. The standard uncertainty factors of 10-fold each have been applied to account for intraspecies variability in toxicological responses and interspecies extrapolation. The *Pest Control Products Act* factor as discussed in the *Pest Control Products Act* Hazard Consideration section, can be reduced to onefold as there were no effects or endpoints of concern related to infants or children and the database was considered complete. Therefore, the composite assessment factor (CAF) is 100.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{5.1 \text{ mg/kg bw/day}}{100} = 0.05 \text{ mg/kg bw/day of dimethenamid-P}$$

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Dermal
For short and intermediate term dermal exposures, the NOAEL in the dermal rabbit toxicity study at 1190 mg/kg bw/day provides the most appropriate endpoint. The standard uncertainty factors of 10-fold each have been applied to account for intraspecies variability in toxicological responses and interspecies extrapolation. The target margin of exposure (MOE) is 100.

Inhalation
For short and intermediate term inhalation exposures, the decreased body weights and liver toxicity in the 90-day dietary rat toxicity study at 110 mg/kg bw/d provide the most appropriate endpoint. The NOAEL for this endpoint was 37 mg/kg bw/d. The standard uncertainty factors of 10-fold each have been applied to account for intraspecies variability in toxicological responses and interspecies extrapolation. The target MOE is 100.

The end use product Frontier Max Herbicide is of moderate toxicity when given as a single oral dose to rats, and is moderately irritating to the eye of rabbits. It also tested positive for dermal sensitization. Consequently, the statements "WARNING–POISON", "Warning–Eye Irritant" and "Potential Skin Sensitizer" are required on the label.

3.4.2 Dermal Absorption

For dimethenamid- P, no chemical specific dermal absorption data were submitted. As the toxicology endpoint for health risk assessment was selected from the dermal route, a dermal absorption factor was not required.

3.4.3 Occupational Exposure and Risk

3.4.3.1 Mixer/Loader/Applicator Exposure and Risk

The mixer/loader/applicator (M/L/A) exposure and risk estimates were generated based on the efficacy supported use pattern and application rates for Frontier Max Herbicide (544–930 g ai/ha) for corn (field, sweet and seed corn–only inbred lines grown in Southern Ontario), soybeans, dry common beans, peanuts grown in Ontario, dry bulb onions, transplanted cabbage and first and second year non-bearing grape vines. Farmers and custom applicators have a potential for dermal and inhalation exposure to dimethenamid-P during mixing, loading and application. These exposures are expected to be of short- to intermediate-term in duration and to occur primarily by the dermal route. Inhalation exposure would be low based on the of dimethenamid-P (1.88×10^{-5} mm Hg at 25°C) which qualifies for North American Free Trade Agreement waiver of $< 7.5 \times 10^{-4}$ mm Hg at 20–30°C for outdoor use.

The previously generated passive dosimetry data in corn were for the racemic form of dimethenamid (Frontier Herbicide). As Frontier Max Herbicide is manufactured from a new technical active ingredient (dimethenamid-P), the mixer/loader/applicator (M/L/A) daily exposures for each use scenario were quantified by a Tier 1 risk assessment approach, using generic unit exposure values (µg ai/kg ai handled) from liquid mix/load and ground boom application files of Pesticide Handlers Exposure Database (PHED). The default area treated per day values (in hectares), based on the Agricultural Statistics in Canada, were used. The estimates were for a mixer/loader or applicator wearing coveralls over single layer of clothing (long pants and a long sleeved shirt) plus gloves.

The dermal exposures were estimated by coupling the unit exposure values with the amount of active handled per day and 100% dermal absorption for the expected scenarios. Low inhalation exposure was estimated by coupling the Pesticide Handlers Exposure Database unit exposure value with the amount of active handled per day with 100% inhalation absorption. The exposure estimates per day were normalized to mg/kg bw/day using 70 kg adult body weight.

Margins of Exposure (MOE) were determined by comparing the dermal and inhalation toxicological endpoints (NOAEL) with the dermal and inhalation exposure estimates. The target MOE for dermal or inhalation route of exposure is 100. The exposure and risk estimates are presented in Table 5, Appendix I. The estimated MOEs exceeded the target of 100 (>4000) and were considered not of concern.

3.4.3.2 Exposure and Risk Assessment for Workers Entering Treated Areas

As Frontier Max Herbicide will be applied early in spring to ground directed soil surface at preemergence or early postemergence to weeds and crops, the postapplication exposure potential to workers entering treated fields to conduct agricultural activities is expected to be low. Early in crop cycle, the expected re-entry activities are scouting, irrigation, weeding and pruning in grapes. As foliage will not be treated, the exposure from dislodgeable foliar surface residue to workers conducting all activities, including harvesting occurring later in the crop cycle in all

crops, detasseling in corn or cane turning and girdling in grapes would be negligible. In addition, the pre-harvest interval (PHI) for transplanted cabbage, peanuts and grapes is more than 60 days. A dermal contact with the treated soil may occur during tasks that are associated with handling soil such as weeding, scouting, irrigating and transplanting cabbage. The exposure is more likely for a short-term duration, primarily by the dermal route. Based on the non-volatile nature of dimethenamid-P, the potential for inhalation exposure is negligible and therefore was not quantified.

There are no chemical-specific soil/foliage dissipation data with which to determine the potential exposure and risks to re-entry workers in treated fields. No transfer coefficients for soil-bound residues are available. Therefore, workers exposure to treated soil/plants was generated by using a Tier 1 approach for foliar treatment, coupling default dislodgeable foliar residue values (20% of the application rate available for dislodging on the day of application and 10% degradation per day) with the activity specific transfer coefficients (TCs) for a specific re-entry activity. Default values for body weight (70 kg) and dermal absorption (100%) were used. The duration of a work day for these activities was assumed as eight hours. Margins of exposure were estimated using the dermal NOAEL of 1190 mg/kg bw/day. The postapplication exposure and risk estimates on the day of application are presented in Table 6, Appendix I.

The MOEs exceed the target of 100 (>300) and are not of concern. No quantitative risk assessment based re-entry interval (REI) is required. However, a default REI of 24 hours is required to address the severity of acute hazards of the proposed formulation and to allow for residues to dry before re-entering a treated field.

3.4.4 Residential Exposure and Risk Assessment

As residential uses were not requested, the residential exposure and risk assessment was not required.

3.4.5 Bystander Exposure and Risk

The product will be handled mainly by workers and application is limited to agricultural crops, under conditions which minimize the spray drift to areas of human habitation. Therefore, bystander exposure and risk can be expected to be much less than that of field workers, and is not of concern.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The field corn metabolism, the rat metabolism and the soil metabolism of dimethenamid-P and dimethenamid (racemic mixture), were demonstrated to be quantitatively and qualitatively the same (same metabolic pathways and same metabolites), with the primary pathway for the

metabolism of dimethenamid and dimethenamid-P being via glutathione conjugation. Therefore, all the residue data generated with dimethenamid can be bridged to dimethenamid-P.

The residue definition for risk assessment and enforcement in plant products and poultry commodities is the parent compound, dimethenamid. The residue definition in all other animal commodities is dimethenamid and the metabolites M7, M17 and M25. The GC-TSD or GC-MS enforcement analytical method is valid for the quantification of dimethenamid residues in various plant matrices. The residues of dimethenamid are stable when stored in a freezer at -20°C for 24 months in field corn matrices and for 16 months in soybean matrices. Raw agricultural commodities of corn, soybeans and peanuts were processed, but were not further analyzed due to the lack of quantifiable residues when treated at fivefold the proposed application rate. Supervised residue trials conducted throughout Canada and the United States using end-use products containing dimethenamid at the approved and exaggerated rates in field corn, sweet corn, soybeans, dry common beans, dry bulb onions, peanuts and cabbage are sufficient to support the maximum residue limits.

3.5.2 Dietary Risk Assessment

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.0), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic analysis: MRLs for all crops. The basic chronic dietary exposure from all supported dimethenamid and dimethenamid-P food uses only, for the total population is 1.9% of the acceptable daily intake (ADI). The PMRA estimates that aggregate chronic dietary exposure to dimethenamid and dimethenamid-P from food and water is 2.9% of the ADI for the total population. The highest exposure and risk estimate is for children 1–2 years old at 10.1% of the ADI. Aggregate exposure from food and water is considered acceptable.

3.5.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified. Therefore, no acute dietary exposure assessment was conducted.

3.5.3 Aggregate Exposure and Risk

The aggregate risk for dimethenamid and dimethenamid-P consists of exposure from food and drinking water sources only (section 3.5.2.1). There are no residential uses.

3.5.4 Maximum Residue Limits

The MRLs established to cover residues of dimethenamid will be used to cover residues of dimethenamid-P as the enforcement analytical method does not differentiate between the different isomers of dimethenamid.

The nature of the residues in animal and plant matrices, analytical methodology, field trial data and the chronic dietary risk estimates are summarized in Tables 1, 7 and 8 in Appendix I.

4.0 Impact on the Environment

Environmental risks involving the use of the herbicide dimethenamid-P technical grade active ingredient and its end use product, Frontier Max Herbicide, was evaluated by using studies conducted with dimethenamid-P and with racemic dimethenamid as a surrogate. Dimethenamid-P enters the environment when its end use product is used as a herbicide for various crops. The end use product is intended to be used once per season at the maximum rate of 930 g a.i./ha for pre-plant soil, pre-emergence, pre-transplant and/or early post-emergence treatments by ground application.

Dimethenamid-P enters the terrestrial environment by direct application on plants and soil. Hydrolysis and photolysis are not expected to be important routes for the transformation of dimethenamid-P. Biotransformation is expected to be the major route for the transformation of dimethenamid-P in soil. It is non-persistent in aerobic soil with the DT_{50} of 7.8 days and moderately persistent in anaerobic soil with the DT_{50} of 59 days .The major transformation products are M23 and M27 together with several minor transformation products (Appendix I, Table 9). Under terrestrial field conditions, dimethenamid-P was non-persistent to slightly persistent in soil with the DT_{50} of 7–43 days (Appendix I, Table 9.1).

Its low vapour pressure (1.88×10^{-5} mm Hg) and Henry's law constant ($1/H = 5.19 \times 10^{6}$) indicate that dimethenamid-P is unlikely to be volatile in the environment. Dimethenamid-P has a low potential for bioaccumulation in the terrestrial environment based on its low K_{ow} of 1.89.

Dimethenamid-P has the potential for leaching in terrestrial environments. It is very soluble in water (1449 mg/L at 25°C). Dimethenamid-P has moderate to high mobility in soil with the adsorption K_{foc} of 90–474. The leaching assessment reveals that dimethenamid-P satisfied all of the criteria set out by Cohen *et al.* (1984) except for K_d and K_{oc} values in some soils and the groundwater ubiquity score was calculated to be 1.2 to 3.3, indicating that dimethenamid-P is in the range of non-leacher to leacher. Under the terrestrial field conditions, dimethenamid-P was detected in soil to a maximum depth of 30 cm. Water monitoring data using racemic dimethenamid as a surrogate indicate that dimethenamid-P can be found in surface water, and its transformation products can be found in both ground water and surface water (Appendix II, Table 1, 2, 3).

Dimethenamid-P enters the aquatic environment by potential drift and run-off after terrestrial applications. In the aquatic environment, biotransformation, rather than hydrolysis or

phototransformation, is expected to be an important route in the transformation of dimethenamid-P. Dimethenamid-P is slightly persistent under aerobic (DT_{50} = 20–37 days) and anaerobic aquatic conditions (DT_{50} = 35 days) (Appendix I, Table 9.2). Major transformation products were identified as M3 and M13 (Appendix I, Table 9).

4.2 Effects on Non-Target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties, environmental fate properties and the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates and plants. Toxicity endpoints used in risk assessments are adjusted with uncertainty factors to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity) and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats), and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Effects on Terrestrial Organisms

The majority of the terrestrial toxicity endpoints were determined with dimethenamid-P, except for studies on the acute toxicity to earthworm and honeybees and reproductive toxicity to birds and rats, in which the toxicity was determined with racemic dimethenamid, as the surrogate (Appendix I, Table 10.1). Studies for the following group of organisms were assessed:

- invertebrates: one earthworm species, one bee species and two other arthropods
- vertebrates: two birds and three mammals
- non-target vascular plants: ten species

Terrestrial Invertebrates

The LC_{50} for the earthworm (*Eisenia foetida*) to dimethenamid-P was determined to be 250 mg a.i./kg. The NOEC for the earthworm to the major transformation products, M23 and M27, was determined to be greater than 1264 mg a.i./kg (as per the European Union (EU) monograph). Risk quotients calculated for the screening level did not exceed the level of concern (Appendix I, Table 10.1). The use of dimethenamid-P is not expected to pose a risk to earthworms.

Dimethenamid-P is relatively non-toxic to honey bees according to the classification of Atkins *et al* (1981)[5] with acute contact and acute oral LD_{50}s being 94 µg a.i./bee and > 1000 µg a.i./bee, respectively. According to Atkins *et al.* (1981), the LD_{50} in micrograms per bee (µg a.i./bee) can be converted to the equivalent application rate in kg a.i. /ha by multiplying µg/bee by 1.12. After conversion, the acute contact LD_{50} value is 105.3 g a.i./ha and the acute oral LD_{50} values is > 1120 g a.i./ha. Risk quotients, calculated at the screening level assessment where the EEC is the proposed maximum application rate of 930 g a.i./ha, did not exceed the level of concern (Appendix I, Table 11.1). The use of dimethenamid-P is not expected to pose an acute risk to bees on a contact or oral basis.

Toxicity studies for two other beneficial arthropods, a parasitoid adult (*Aphidius rhopalosiphi*) and a predatory mite nymph (*Typhlodromus pyri*), were reviewed by the European Union. An emulsifiable concentrate formulation containing 64% dimethenamid-P was used. The results were summarized in the European Union monograph and considered in this assessment. At the highest test concentration (896 g a.i./ha), no parasitoids survived on glass substrate after 48-hour exposure, but all survived on barley substrate with the reduction of parasitation capacity by 46%. The fertility of the predators was reduced by 27% after 14-days of exposure on glass substrate with 11% mortality. Risk quotient was not calculated as no appropriate endpoints were generated in the studies. Providing that the end use product of dimethenamid-P is to be applied for pre-plant, pre-emergent, pre-transplant and early post-emergence treatments only, the exposure to beneficial arthropods is considered to be limited. Therefore the use of dimethenamid-P is not expected to pose an unacceptable risk to beneficial arthropods, based on this proposed use pattern.

Terrestrial Plants

Seedling emergence and vegetative vigour studies on ten vascular plant species were reviewed. The seedling emergence is more sensitive to dimethenamid-P than is the vegetative vigour. Perennial ryegrass was shown to be the most sensitive species for both seedling emergence and vegetative vigour with EC_{25} of 7.7 g a.i./ha and 26 g a.i./ha, respectively (Appendix I, Table 10.1). Risk quotients at the screening level are calculated to be 121 for the seedling emergence and 36 for the vegetative vigour, greatly exceeding the level of concern (Appendix I, Table 11.1). The refined risk quotients calculated using 6% spray drift (ASAE medium spray quality) at 1 m downwind from the edge of application still exceed the level of concern (RQ = 7.3 and 2.2), which triggered a further refined risk assessment with a species sensitivity distribution approach. With this approach, a new endpoint of 5% hazard concentration (HC_5) that

[5] Atkins EL; Kellum D; Atkins KW. 1981. Reducing pesticide hazards to honey bees: mortality prediction techniques and integrated management techniques. Univ Calif, Div Agric Sci, Leaflet 2883. 22 pp.

is aimed at protecting 95% of terrestrial plant species was determined to be 13.7 g a.i./ha for the seedling emergence. Using this HC_5 value, the risk quotient determined for terrestrial plants is 4.07 off-field using 6% spray drift of the maximum rate, which still exceeds the level of concern. Using the HC_5 value, a 3 m buffer zone was determined in order to mitigate the risks to non-target terrestrial plants when using dimethenamid-P (Appendix I, Table 11.4).

Terrestrial Vertebrates

For birds, acute oral toxicity studies using bobwhite quail and dietary and reproductive toxicity studies using bobwhite quail and mallard duck, were submitted to the PMRA. Bobwhite quail appeared to be more sensitive than mallard duck with an acute oral LD_{50} of 1068 mg a.i./kg bw, dietary LC_{50} of >5620 mg a.i./kg and the reproduction NOEC of 900 mg a.i./kg diet based on the effect on the egg-shell thickness (Appendix I, Table 10.1). These toxicity endpoints were converted into daily doses with default food ingest rates and body weights, and were then compared to the daily exposure estimates to calculate the risk quotients. The exposure estimates for birds are calculated based on the body weight of the organisms and the amount and type of food consumed. The screening level risk assessment considers a set of generic body weights (20, 100 and 1000 g for birds) and food preferences. Calculated risk quotients at the screening level assessment did not exceed the LOC for all birds with selected generic weight, except for 1000 g herbivore birds (RQ = 1.12) (Appendix I, Table 11.2). This RQ does not exceed the level of concern in a refined assessment when 6% spray drift at 1 m downwind from the edge-of-field of application is considered. Dimethenamid-P is intended to be used in early cropping seasons for pre-plant, pre-emergence, pre-transplant and early post-emergence treatments. It is unlikely that the herbivore birds would eat exclusively the plant items treated at the maximum exposure concentrations. Given the short half-lives of dimethenamid-P and the low on-field risk quotient, the use of dimethenamid-P is not expected to pose an unacceptable off-field or on-field risk to birds.

For mammals, toxicity studies using rats, rabbits and dogs were submitted to the PMRA. The most conservative endpoints for dimethenamid-P were the acute oral LD_{50} of 466 mg a.i./kg bw, the dietary NOAEL of 37 mg/kg bw/d and the developmental NOAEL of 25 mg/kg bw/d for rats (Appendix I, Table 10.1). These endpoints were directly used for the calculation of risk quotients for acute, dietary and reproductive toxicity, respectively. The exposure estimates for mammals are calculated with the same approach as described above for birds, but the generic body weights for mammals are selected to be 15, 35 and 1000 g. The initial screening level assessment identified potential risks of adverse acute effects to 35 g and 1000 g mammalian herbivores, adverse dietary effects to 35 g mammalian insectivores, granivores, frugivores, 1000 g mammalian insectivore and frugivores, and adverse reproductive effects to 15 g insectivores, 35 g herbivores and 1000 g mammalian herbivores (RQ = 1.06–6.20) (Appendix I, Table 11.2). These risks did not exceed the level of concern in a refined assessment when the 6% spray drift for 1 m downwind is applied. However, two risks identified at initial screening level for the adverse dietary effects to 35 g and 1000 g mammalian herbivores (RQ = 21.28–38.66) still exceed the LOC using 6% spray drift off-field scenario with leaves and leafy crops as food sources (RQ = 1.28–2.32). When short range grass is used as a food source, the RQs for these herbivores are calculated to be 1.33 and 0.73 for the off-field spray drift scenario. This assessment for mammals was conducted assuming maximum exposure concentration on food

items immediately after application, and mammals foraged exclusively on the single category of a particular food. Given that dimethenamid-P is intended to be used in early cropping seasons for pre-plant, pre-emergence, pre-transplant and early post-emergence treatments, and that half-lives for dimethenamid-P are short, it is unlikely that a small mammal would eat exclusively food items treated at the maximum exposure concentrations. The refined assessment is representative of a highly conservative scenario. However, the use of dimethenamid-P may still pose certain level of risks to small wild mammals, especially in fields. A label statement indicating the toxicity to small mammals is required.

4.2.2 Effects on Aquatic Organisms

All aquatic toxicity studies were conducted with dimethenamid-P except for the toxicity to chronic *Daphinia* and the early life-stage rainbow trout, for which racemic dimethenamid were used (Appendix I, Table 10.2). Studies for each group of organisms in freshwater and marine environments are:

Freshwater:

- invertebrates: one *Daphnia* species
- algae: three species
- vertebrates: two fish species
- non-target plants: one species
- amphibian: no studies, but using fish as surrogate

Marine:

- invertebrates: one mysid species
- algae: one species
- vertebrates: one fish species

Aquatic organisms can be exposed to dimethenamid-P as a result of spray drift and/or run-off. To assess the potential effects from exposure to dimethenamid-P and its transformation products, environmental exposure estimates at the screening level in the aquatic environment were calculated based on direct application to water and assuming instantaneous and complete mixing within the water body. The calculated EECs were those determined in 15 cm depth of water body for amphibians and 80 cm depth of water body for all other aquatic organisms. The laboratory endpoints were adjusted using uncertainty factors to account for differences in species sensitivity and protection goals (e.g. community, population and individual). When RQs exceed the level of concern at the initial screening level assessment, a refined risk assessment for freshwater or marine organisms was conducted using EEC values calculated for spray drift of 6% (ASAE medium spray quality) of the maximum application rate, or using the most conservative EEC value calculated from runoff water modelling ecoscenarios.

Aquatic Invertebrates–Freshwater and Marine

The acute toxicity of dimethenamid-P to *Daphnia magna* demonstrated mortality with a 48-hour LC_{50} of 12 mg a.i./L and the chronic NOEC was estimated to be 1.02 mg a.i./L. A similar acute toxicity to marine invertebrate *Mysidopsis bahia* was determined to be a EC_{50} of 3.2 mg a.i./L (Appendix I, Table 10.2). Calculated RQs for both freshwater and marine invertebrates indicate

that the LOCs for acute and chronic effects were not exceeded (Appendix I, Table 11.3). Therefore, the use of dimethenamid-P is not expected to pose an unacceptable risk to aquatic invertebrate populations.

Fish–Freshwater and Marine

Acute toxicity studies with dimethenamid-P were submitted for two freshwater fish and one marine fish species. Endpoints for mortality were the following: rainbow trout, 96-hour LC_{50} = 6.3 mg a.i./L; bluegill sunfish, 96-hour LC_{50} = 10 mg a.i./L; sheepshead minnow, 96-hour LC_{50} = 12 mg a.i./L. The NOEC for early life-stage toxicity of dimethenamid-P to rainbow trout was estimated to be 0.3 mg a.i./L (Appendix I, Table 10.2). Calculated risk quotients for both freshwater and marine fish demonstrate that LOCs for acute and early life-stage effects were not exceeded (Appendix I, Table 11.3). Therefore, the use of dimethenamid-P is not expected to pose an unacceptable risk to fish populations.

Amphibian–Freshwater

No amphibian studies were available for the risk assessment for dimethenamid-P. Fish endpoints were used for the risk assessment for amphibians. The RQ calculated with acute endpoints did not exceed the LOC. The RQs calculated with early life-stage NOEC exceeded LOC at screening level assessment. The refined assessments using 6% spray drift and runoff modelling scenarios were conducted, and the LOCs were not exceeded (Appendix I, Table 11.3). Therefore, the use of dimethenamid-P is not expected to pose an unacceptable risk to amphibians.

Aquatic Algae–Freshwater and Marine

Acute studies for three freshwater and one marine algae were submitted to the PMRA for dimethenamid-P. The most conservative endpoints for the freshwater algae (green algae) and marine algae (marine diatom) were EC_{50} = 0.017 mg a.i./L and 0.12 mg a.i./L respectively (Appendix I, Table 10.2). The calculated RQs for the acute exposure to freshwater algae exceeded the LOC at initial screening level and for the runoff modelling scenarios. However, the RQ did not exceed the LOC in the refined risk assessment using 6% spray drift (ASAE medium spray quality) at the maximum application rate (930 g a.i./ha) (Appendix I, Table 11.3). The calculated RQ for the marine algae (marine diatom) exceeded the LOC at the screening level assessment, but did not exceed the LOC in the refined assessment using 6% spray drift and for the runoff modelling scenarios. To reduce the risk of dimethenamid-P to freshwater algae from runoff, a label statement on the toxicity to aquatic organisms is required.

Aquatic Plants–Freshwater

A 14-day study for freshwater vascular plant, *Lemna gibba*, was submitted to the PMRA for dimethenamid-P. The endpoint for biomass was determined to be an EC_{50} of 0.0089 mg a.i./L (Appendix I, Table 10.2). The calculated RQs for the exposure to vascular plants exceeded the LOC at the initial screening level risk assessment. Refined assessments using runoff modelling scenarios and 6% spray drift (ASAE medium spray quality) at the maximum application rate (930 g a.i./ha) were conducted. The LOC were exceeded (RQ = 7.9 and 1.6 respectively) in both refined assessments (Appendix I, Table 11.3). Therefore a label statement on the toxicity to aquatic organisms is required, and a 1 m buffer zone is determined to protect the aquatic habitat from the use of dimethenamid-P.

5.0 Value

Data from a total of 105 efficacy trials were available for review. Trials were conducted on corn (78 trials), soybeans (17 trials) and dry common beans (10 trials). Frontier Max Herbicide based treatments, including Frontier Max Herbicide alone or in tank mixtures, were directly compared to corresponding Frontier Herbicide based treatments in 67 trials at the same application rate based on the s-isomer. Only Frontier Max Herbicide based treatments were assessed in the remaining 38 trials. All trials were conducted in Quebec and Ontario in 1996, 1997, 1998, 1999, 2001 and 2005. The Herbicide treatments were applied pre-plant incorporated in nine trials, pre-emergence in 44 trials and early post-emergence in 52 trials using small plot application equipment.

Although the rate for Frontier Max Herbicide varies depending on soil texture, organic matter content and application timing; the efficacy data were analyzed by directly comparing Frontier Max Herbicide based treatments to corresponding Frontier Herbicide based treatments, over different soil textures and application timings and a wide range of organic matter contents. The efficacy of Frontier Max Herbicide alone or in tank mixture with atrazine, Roundup Original, Pursuit or Impact + atrazine for control of green foxtail, yellow foxtail, smooth crabgrass, large crabgrass, barnyard grass, fall panicum, witch grass, redroot pigweed, common lamb's-quarters, common ragweed and wild buckwheat, was visually assessed and reported as a percentage. Efficacy was assessed at various times throughout the growing season.

5.1 Acceptable Efficacy Claims

5.1.1 Frontier Max Herbicide Alone

Adequate data were submitted to establish agronomic equivalency, in term of product efficacy, between Frontier Max Herbicide and Frontier Herbicide at the same rate based on the s-isomer. Therefore the weed control claims listed on the Frontier Herbicide label are acceptable to appear on the Frontier Max Herbicide label (Table 5.1.1).

Table 5.1.1 Weed Control Claims for Frontier Max Herbicide

Foxtail (green, yellow and giant) Crabgrass (smooth and large) Old witchgrass Barnyard grass	Fall panicum Redroot pigweed* Eastern black nightshade** Yellow nutsedge***

*Pre-plant incorporated (860–963 mL/ha) or pre-emergence (963 mL/ha) only;
**Pre-plant incorporated or pre-emergence (963 mL/ha) only;
***Pre-plant incorporated only (963 mL/ha. Lower rates provide suppression only).

Application rates for Frontier Max Herbicide based on soil texture, organic matter content and application timings are shown in Table 5.1.2.

Table 5.1.2 Rates of Frontier Max Herbicide for Pre-Emergence and Post-Emergence Application Timings

Soil Type	Application Rate		
	<3% Organic Matter	3–6% Organic Matter	7–10% Organic Matter
Course Textured Soils	756 mL/ha (544 g a.i./ha)	756 mL/ha (544 g a.i./ha)	860 mL/ha (619 g a.i./ha)
Medium Textured Soils	756 mL/ha (544 g a.i./ha)	860 mL/ha (619 g a.i./ha)	963 mL/ha (693 g a.i./ha)
Fine Textured Soils	756 mL/ha (544 g a.i./ha)	860 mL/ha (619 g a.i./ha)	963 mL/ha (693 g a.i./ha)

The application rate for pre-plant incorporated treatment is 860 to 963 mL/ha (619 to 693 g a.i./ha).

The application rate specifically for suppression of yellow nutsedge in dry onions at the loop stage grown on muck soil is 1.29 L/ha (930 g a.i./ha).

5.1.2 Herbicide Tank-Mix Combinations

Adequate data were provided to establish agronomic equivalency, in term of product efficacy, of Frontier Max Herbicide to Frontier Herbicide in tank mix with atrazine, Roundup Original, Pursuit or Impact + atrazine. Therefore, the tank mix partner products that are listed on the Frontier Herbicide label, as well as the tank mix of Frontier Herbicide + Impact + atrazine, that are included on the Impact label, are acceptable to appear on the Frontier Max Herbicide label (Table 5.1.3).

Table 5.1.3 Tank Mix Partners for Frontier Max Herbicide

Crops	Application Timing	Tank Mix Partners (rate per hectare)
Corn (conservation tillage systems)	Pre-plant	Atrazine (0.99–1.53 kg a.i.) or Roundup Original (2.5 L) or Roundup Original + Banvel II Herbicide (2.5 L + 1.25 L) or Roundup Original + Marksman Herbicide (2.5 L + 4.5 L) or Roundup Original + atrazine (2.5 L + 0.99–1.53 kg a.i.)
	Pre-emergence	Banvel II Herbicide (1.25 L) or Marksman Herbicide (4.5 L) or Atrazine (0.99–1.53 kg a.i.) or Roundup Original (2.5 L) or Roundup Original + Banvel II Herbicide (2.5 L + 1.25 L) or Roundup Original + Marksman Herbicide (2.5 L + 4.5 L) or Roundup Original + atrazine (2.5 L + 0.99–1.53 kg a.i.)
Field corn	Pre-plant incorporated	Atrazine (0.99–1.53 kg a.i.)
	Pre-emergence	Atrazine (0.99–1.53 kg a.i.) or Banvel II Herbicide (1.25 L) or Marksman Herbicide (4.5 L)
	Early post-emergence	Atrazine (0.99–1.53 kg a.i.) or Banvel II Herbicide (1.25 L) or Marksman Herbicide (3.7–4.5 L) or Impact + atrazine (37 mL + 500 g a.i.)
Soybeans (conservation tillage systems)	Pre-plant or after seeding but before crop emergence	Roundup Original (2.5 L)
Soybeans	Pre-emergence	Pursuit Herbicide (312-420 mL)

5.2 Phytotoxicity to Host Plants

Data from 123 trials were available for review, 101 of which were combined efficacy and crop tolerance trials and 22 of which were dedicated crop tolerance trials.

Field Corn: Crop safety of field corn was assessed in 98 trials. The herbicide treatments were applied as pre-plant incorporated in six trials, pre-emergence in 23 trials and early

post-emergence in 69 trials. A total of 23 corn hybrids were assessed for tolerance to Frontier Max Herbicide alone or in tank mixture with atrazine, Marksman, Roundup Original or with both Impact Herbicide and atrazine in these trials. Frontier Max Herbicide based treatments were directly compared to Frontier based treatments in 61 trials. Frontier Max Herbicide based treatments only were assessed in the remaining 37 trials. Crop injury to corn was visually assessed two to three times per growing season and corn grain yield was reported in 18 trials.

Soybeans: Crop safety of soybeans was assessed in 15 trials. The herbicide treatments were applied as pre-plant incorporated in four trials and pre-emergence in 11 trials. A total of six soybean varieties were assessed for tolerance to Frontier Max Herbicide alone or in tank mixture with Pursuit Herbicide and Roundup Original. Frontier Max Herbicide treatments were directly compared to Frontier Herbicide treatment in all 15 trials. Crop injury to soybeans was visually assessed two to three times per growing season and soybean yield was reported in four trials.

Dry Common Beans: Crop safety of dry common beans was assessed in 10 trials. The herbicide treatments were applied as pre-plant incorporated in four trials and pre-emergence in six trials. Two bean marketing classes (five varieties) were assessed for tolerance to Frontier Max Herbicide and directly compared to Frontier Herbicide. Crop injury to dry common beans was visually assessed two to three times per growing season and bean grain yield was reported in seven trials.

5.3 Supported Claims

Adequate data were submitted to establish the agronomic equivalency, in term of crop safety, between Frontier Max Herbicide and Frontier Herbicide when applied alone or in combination with the same tank mix partners. Therefore, all the host claims listed on the Frontier Herbicide label are acceptable to appear on the Frontier Max Herbicide label (Table 5.2.1).

Table 5.2.1 Host Claims for Frontier Max Herbicide

Crops	Application Timing	Frontier Max Herbicide (g a.i. per hectare)
Corn (Eastern Canada)–conservation tillage systems	Pre-plant or after seeding but before crop emergence	544–693
Field Corn (Eastern Canada)	Pre-plant incorporated	619–693
	Pre-emergence and early post-emergence (emergence to 3-leaf)	544–693
Field Corn (Prairie provinces of Western Canada)	Pre-plant incorporated	619–693
Sweet Corn (Eastern Canada)	Pre-plant incorporated	619–693

Crops	Application Timing	Frontier Max Herbicide (g a.i. per hectare)
	Pre-emergence application	544–693
Seed Corn (Ontario)	Pre-emergence application	544–619
Soybeans (Eastern Canada)– conservation tillage systems	Pre-plant or pre-emergence	544–693
Soybean (Eastern Canada)	Pre-plant incorporated	619–693
	Pre-emergence application	544–693
Dry Common Beans*	Pre-plant incorporated	619–693
	Pre-emergence application	544–693
Transplanted cabbage	Pre-transplant treatment	544–693
Peanuts (Ontario)	Pre-plant incorporated	619
	Pre-emergence application	544–619
Non-bearing grape vines	Applied directly under vines	693
Dry bulb onions	At the loop stage of the crop	930

*Dry common bean varieties may vary in their tolerance to herbicides, including Frontier Max Herbicide. Since not all dry common bean varieties have been tested for tolerance to Frontier Max Herbicide, first use of Frontier Max Herbicide should be limited to a small area of each variety to confirm tolerance prior to adoption as a general field practice. Additionally, consult seed supplier for information on the tolerance of specific varieties of dry common beans to Frontier Max Herbicide.

5.4 Acceptable Claims for Rotational Crops

As agronomic equivalency between Frontier Max Herbicide and Frontier Herbicide was established based on efficacy and crop safety data, no differences in rotational crop safety would be expected between Frontier Max Herbicide and Frontier Herbicide. Therefore, rotational crop claims on the Frontier Herbicide label are acceptable for Frontier Max Herbicide.

5.5 Sustainability

5.5.1 Survey of Alternatives

Frontier Max Herbicide (Group 15), intended to replace Frontier Herbicide provides the same efficacy and crop tolerance as Frontier Herbicide. However, as Frontier Max Herbicide contains primarily the s-isomer, it reduces the total dimethenamid load into the environment by 45%. Frontier Max Herbicide provides Canadian growers a pest management tool to control grasses and certain broadleaf weeds in a number of crops.

The key herbicide options currently available for weed control in the labeled crops for Frontier Max Herbicide are summarized in (Appendix I, Table 12).

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Frontier Max Herbicide is compatible with current management practices as it can be applied as a stand alone treatment or in tank mix with other herbicides. The stand alone option provides growers the opportunity to control those weeds susceptible to dimethenamid-P. The tank mixing options available with Frontier Max Herbicide allows growers the opportunity to control a broad spectrum of weeds with a one-pass treatment.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Repeated use of herbicides having the same mode of action in a weed control program increases the probability of naturally selecting the biotypes, (a group of plants within a species which has biological traits that are not common to the population as a whole) with less susceptibility to the herbicides using that mode of action. Therefore, Frontier Max Herbicide should be tank-mixed with herbicides with a different mode of action or be used in rotation with herbicides having different modes of action.

The Frontier Max Herbicide label includes the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

5.5.4 Contribution to Risk Reduction and Sustainability

The registration of Frontier Max Herbicide will allow for a reduced amount of total dimethenamid to be applied to field crops as compared to the currently registered racemic mixture of Frontier Herbicide. This will result in a reduced herbicidal load on the environment and reduced worker exposure.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, dimethenamid-P was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of dimethenamid-P were also considered, including transformation products formed in the environment, contaminants in the technical product and the formulants in the end-use product. Dimethenamid-P and its transformation products were evaluated against the following Track 1 criteria: persistence in soil ≥182 days; persistence in water ≥182 days; persistence in sediment ≥365 days; persistence in air ≥2 days; evidence of atomospheric transport to remote regions such as arctic; bioaccumulation log Kow ≥5 and/or BCF or BAF ≥5000. In order for dimethenamid-P or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The technical product and end-use product, including formulants, were assessed against the contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3 Contaminants of Health or Environmental Concern.* The PMRA has reached the following conclusions:

- Dimethenamid-P does not meet the Track 1 criterion for persistence, as its half-life values in water (20–37 days), soil (7.8–59 days) are below the Track 1 criteria. Dimethenamid-P does not meet the Track 1 criterion for persistence in air because volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on its vapour pressure (1.88×10^{-5} mm Hg) and Henry's law constant (4.7×10^{-9} atm.m^3.mol^{-1}). Dimethenamid-P does not meet the Track 1 criterion for bioaccumulation, as its octanol-water partition coefficient (log K_{ow} = 1.89) and bioconcentration factor (BCF = 57) are below the Track 1 criterion. Therefore, dimethenamid-P does not meet the Track 1 criteria and is not considered a Track 1 substance.

- Dimethenamid-P does not form any transformation products that meet the Track 1 criteria. Only limited chemistry, fate and toxicity information was available for the dimethenamid-P transformation products, including major transformation products M3, M13, M23 and M27. These compounds are formed by dechlorination and subsequent oxidation and/or sulfination of the parent compound, and are structurally similar to the parent that has log K_{ow} of 1.89. Thus, transformation products are unlikely to have the properties of a TSMP track 1 substance.

- There are no Track 1 contaminants in the technical product or end use product.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, formulants and contaminants in the technical and end-use products are assessed against the formulants and contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. This list of formulants and contaminants of health and environmental concern are identified using existing policies and regulations including: the federal Toxic Substances Management Policy; the Ozone-depleting Substance Regulations,

1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol); and the PMRA Formulants Policy as described in the PMRA Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*. The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* is maintained and used as described in the PMRA Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* consists of three parts:

- Part 1: Formulants of Health or Environmental Concern;
- Part 2: Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions; and
- Part 3: Contaminants of Health or Environmental Concern.

The contaminants to which Part 3 applies meet the federal Toxic Substances Management Policy criteria as Track 1 substances, and are considered in section 6.1. The following assessment refers to the formulants and contaminants in Part 1 and Part 2 of the list.

Dimethenamid-P Technical Herbicide and the end-use product Frontier Max Herbicide do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. However, the end use product, Outlook, contains aromatic petroleum distillates, a list 2 formulant. Therefore, the label for the end use product will include the following label statement:

- This product contains an active ingredient and aromatic petroleum distillates which are toxic to aquatic organisms.

Dimethenamid-P Technical Herbicide contains trace amounts of residual solvents heptane (< 0.0005%, CAS # 142-82-5) and 1,1,1-2-tetrachloroethane (0.064%, CAS # 630-20-6), which are the Part 5 and Part 1 Environment NPRI (National Pollutant Release Inventory) Substances respectively. The reporting thresholds are 1 tonne for heptane and 10 tonne and concentration of 1% by weight for 1,1,1-2-etrachloroethane. By considering the negligible concentrations, reporting thresholds for these two contaminates are not expected to be met for the end use product containing dimethenamid-P on the basis of proposed use patterns.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for dimethenamid-P demonstrated that toxicity is similar to racemic dimethenamid. In subchronic and chronic studies on laboratory animals, the primary target was the liver. There was no evidence of carcinogenicity in rats or mice after longer-term dosing. There was no evidence of increased susceptibility of the young in reproduction or

developmental toxicity studies. s-Dimethenamid is not considered to be a neurotoxicant. The studies submitted for dimethenamid-P showed a strong correlation in terms of toxicity to racemic dimethenamid. The s-isomer is therefore considered toxicologically equivalent to the racemic technical active.

Mixers, loaders, applicators and workers entering treated areas are not expected to be exposed to levels of Frontier Max Herbicide that may result in unacceptable risk when Frontier Max Herbicide is used according to label directions. The personal protective equipment stated on the label is adequate to protect workers.

The nature of the residue in corn, soybean, sugarbeet plants and in animals (hen and goat) is adequately understood. The residue definition is dimethenamid in plants and poultry commodities and dimethenamid and metabolites M7, M17 and M25 in all other animal commodities. The proposed use of dimethenamid and dimethenamid-P on crops listed on the labels does not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Animal studies revealed no acute health effects. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health. The PMRA recommends that the MRLs established to cover residues of dimethenamid be used to cover residues of dimethenamid-P, as the enforcement analytical method cannot differentiate between the different isomers of dimethenamid.

7.2 Environmental Risk

The use of dimethenamid-P and its end use product, Frontier Max Herbicide, does not pose an unacceptable risk to terrestrial or aquatic organisms when used according to label directions. Standard environmental label statements and statements on the toxicity to aquatic organisms, plants and small wild mammals must be added on the product labels as precautions. A buffer zone of 3 m is required to for the protection of terrestrial plants and 1 m is required for the protection of aquatic habitats.

7.3 Value

The data submitted are adequate to establish agronomic equivalency, in term of product efficacy and crop safety between Frontier Max Herbicide and the precedent product, Frontier Herbicide. Frontier Max Herbicide controls annual grasses plus redroot pigweed, eastern black nightshade and yellow nutsedge, and may be applied in a tank mix with other herbicides for broad spectrum weed control. Frontier Max Herbicide contains the refined isomer of dimethenamid-P which mainly attributes to herbicidal activity and is intended to replace Frontier Herbicide which is comprised of the racemic mixture of dimethenamid (45:55 of r- and s-stereoisomers). Therefore, application of Frontier Max Herbicide allows for a reduction of the total dimethenamid load into the environment by 45%.

8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Dimethenamid-P Technical Herbicide and Frontier Max Herbicide containing the technical grade active ingredient dimethenamid-P, to control certain annual grassy weeds as well as redroot pigweed, eastern black nightshade and yellow nutsedge in corn, soybeans, dry common beans, dry bulb onions, transplanted cabbage, peanuts and non-bearing grape vines.

An evaluation of available scientific information found that under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
atm	atmosphere
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
DFR	dislodgeable foliar residue
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in the test population)
DT_{75}	dissipation time 75% (the dose required to observe a 75% decline in the test population)
Dw	dry weight
EC_5	effective concentration on 5% of the population
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
EDE	estimated daily exposure
EEC	estimated environmental exposure concentration
ER_{25}	effective rate on 25% of the population
ER_{50}	effective rate on 25% of the population
g	gram
GC	gas chromatography
ha	hectare(s)
Hg	mercury
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%

m^3	metre(s) cubed
mg	milligram
mL	millilitre
MAS	maximum average score
M/L/A	mixing, loading and application
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
REI	restricted entry interval
RSD	relative standard deviation
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TC	transfer coefficient
TGAI	technical grade active ingredient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	Limit of Quantitation (LOQ)	Reference Number
Plant	AM-0840-0790-0	Dimethenamid[1] and Oxalamide	GC-MSD (gas chromatography with mass selective detection)	0.01 ppm (corn matrices)	1234860
	Independent Laboratory Validation of Method Number AM-0840-0790-0	Dimethenamid[1] and Oxalamide	GC-MSD	0.01 ppm (corn grain and forage)	1234861
	AM-0850-0291-0	Dimethenamid[1] and Oxalamide	GC-MSD	0.02 (soybean matrices)	1124973
	BS2304 (Updated Method Number AM-0840-0790-0)	Dimethenamid[1]	GC-TSD (thermionic nitrogen specific detector) or GC-MS	0.01 ppm (corn and soil)	1137396
	AM-0884-0193-1 (Updated Method Number BS2304) Enforcement Method	Dimethenamid[1]	GC-TSD or GC-MS	0.01 ppm (corn including processed commodities)	1041282
	XM-15	Dimethenamid[1]	GC-NPD (nitrogen phosphorus detector)	0.02 ppm (corn and soybean matrices)	1169634
	XM-15B	Dimethenamid[1]	GC-NPD	0.02 ppm (white bean matrices)	1162676
Soil*	XM-14	Dimethenamid /oxalamide	GC/NPD	0.01 ppm	1130677
	TDS BS-4958	Dimethenamid /oxalamide /sulfonate	LC/UV	0.01–0.02 ppm	1130647, 1130712
Sediment*	TDS BS-4958	Dimethenamid /oxalamide /sulfonate	LC/MS/MS	0.01–0.02 ppm	
Water*	AM-0853-0491-0	dimethenamid	GC/NPD	0.05 ppb	1044829
		dimethenamid	GC/MSD	0.05 ppb	
Cattle/ Poultry (fat)	BS-2438	dimethenamid	GC/NPD	0.01 ppm	1130646
Cattle/ Poultry (liver)	BS-2438	dimethenamid	GC/NPD	0.01 ppm	1130646

Table 2 Acute Toxicity of s-Dimethenamid and Its Associated End-use Product (Frontier Max Herbicide)

Study Type	Species	Result	Comment	Reference Number
Acute Toxicity of Dimethenamid-P (Technical)				
Oral	Rat	LD_{50} = 466 mg/kg (combined)	High toxicity	1128684
Dermal	Rabbit	LD_{50} > 2000 mg/kg (combined)	Low toxicity	1128686
Inhalation	Rat	LC_{50} > 2.2 mg/L (combined)	Low toxicity	1128687
Skin irritation	Rabbit	MAS 0.8/8	Slightly irritating	1128690
Eye irritation	Rabbit	MAS 0.7/110	Minimally irritating	1128689
Skin sensitization	Guinea pig	Positive	Skin sensitizer	1128691
Acute Toxicity of Racemic Dimethenamid (Technical)				
Oral	Rat, PEG 200	LD_{50} = 2360 mg/kg (males)	Low toxicity	1079002
	Rat, PEG 200	LD_{50} = 2100 mg/kg (females)	Low toxicity	1079003
	Rat, corn oil	LD_{50} = 1569.8 mg/kg (combined)	Slight toxicity	1079004
	Rat	LD_{50} = 471 mg/kg (combined)	High toxicity	1079005
	Rat	LD_{50} = 397 mg/kg (combined)	High toxicity	1079006
	Rat, combined with corn oil; females only undiluted	LD_{50} = 1250 mg/kg (combined) LD_{50} ~ 500 mg/kg (females)	High toxicity	1079007
Dermal	Rabbit	LD_{50} > 2000 mg/kg (combined)	Low toxicity	1079008
Acute Toxicity of End-Use Product–Frontier Max Herbicide				
Oral	Rat	LD_{50} = 695 mg/kg (combined)	Moderate toxicity	1090482
Dermal	Rabbit	LD_{50} > 2000 mg/kg (combined)	Low toxicity	1090483
Inhalation	Rat	LC_{50} > 2.4 mg/L (combined)	Low toxicity	1090488
Skin irritation	Rabbit	MAS 1.4/8	Slightly irritating	1090490
Eye irritation	Rabbit	MAS 12.3/110 + persistent corneal opacity and ulcerations	Moderately irritating	1090489
Skin sensitization	Guinea pig	Positive	Skin sensitizer	1090497

Studies for racemic dimethenamid are not included above because they were previously reviewed

[a]MAS = maximum average score for 24, 48 and 72 hours

[b]MIS = maximum irritation score

Table 3 Toxicity Profile of Technical Dimethenamid-P

Study Type	Species	Results[a] (mg/kg/day in M/F)	Reference Number
90-day dietary	Rat	NOAEL: 37 mg/kg bw/d LOAEL: 110 mg/kg bw/d Body-weight effects, increased relative liver weights with hepatocellular hypertrophy and multiple hematological effects.	1128693
Developmental toxicity	Rat	**Maternal:** NOAEL: 25 mg/kg bw/d LOAEL: 150 mg/kg bw/d Decreased body weight and food consumption **Developmental:** NOAEL: 150 mg/kg bw/d LOAEL: 300 mg/kg bw/d Presence of a cervical rib at the seventh cervical vertebra	1128694
Reverse gene mutation assay		Negative	1128695
Reverse gene mutation assay		Negative	1128696
Reverse gene mutation assay		Positive, but only TA 100, only–S9, not repeatable in the other three Ames tests	1128697
Reverse gene mutation assay		Negative	1128698
Gene mutations in mammalian cells in vitro		Negative	1128699
In vitro unscheduled DNA synthesis		Negative	1128702
In vitro mammalian chromosomal aberration		Negative	1128700
In vivo mammalian cytogenetics		Negative	1128701
Metabolism	Rat liver, in vitro	In this comparative study, racemic and s-isomer dimethenamid were found to produce the same metabolites, though the relative quantities were only roughly similar, especially M33 (23.0% in racemate, 15.7% s-isomer) and M35 (15.6% racemate, 20.3% s-isomer).	1079010
Studies below were tests performed with racemic dimethenamid			
	Rat	**Absorption** Not examined **Distribution** Not examined **Excretion**	1079012

		Total recovery of radioactivity was greater than 90% of administered dose by 168 hours. Except in the single high dose group, feces accounted for the highest quantities of radioactivity. In bile duct cannulated rats, 75-82% of the radioactive dose was accounted for in the bile. The compound shows evidence of saturation in the bile. Metabolism 22 metabolites were identified. There were some slight differences in the quantities of metabolites between urine and feces, but the vast majority of metabolites were common between the two matrices.	
	Rat liver, in vitro	Confirmation of the formation of M27 and M31.	1128703
	Mice	Confirmation of the formation of the sulfonate metabolite (M27) of dimethenamid in both urine and feces. Presence confirmed.	1128704
	Rats	Confirmation of the formation of the sulfonate (M27), the thioglycolic acid (M32) and the sulfoxide of the thioglycolic acid metabolites (M31) of dimethenamid in both urine and feces. The sulfoxide of thioglycolic acid was only detected in urine, but the thioglycolic acid was not confirmed in any excreta.	1128705
	Mice	Confirmation of the formation of the sulfoxide of the thioglycolic acid metabolite (M31) of dimethenamid in both urine and feces. Presence of M31 confirmed.	1128706

Studies for racemic dimethenamid are not included above because they were previously reviewed
[a]Effects observed in males as well as females unless otherwise reported

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Dimethenamid-P

Exposure Scenario	Dose (mg/kg bw/day)	Study	Endpoint	CAF[1] or Target MOE[2]
Acute dietary	NOAEL = N/A			
	ARfD = None			
Chronic dietary	NOAEL = 5.1 mg/kg bw/d	Chronic rat	Hyperplasia of the parathyroid and bile duct	100
	ADI = 0.05 mg/kg bw/d			
Short and intermediate term dermal	NOAEL = 1190 mg/kg bw/d	21-day rat dermal toxicity	None	100
Short and intermediate term dermal	NOAEL = 37 mg/kg bw/d	90-day rat dermal toxicity	Decreased body weights and liver toxicity	100

[1]Dietary scenerios
[2]Exposure scenerios

Table 5 Mixer/Loader/Applicator Exposure and Risk

Crop	Exposure Scenario	Maximum Application Rate (kg ai/ha)[1]	Area Treated Per Day (ha)[2]	Amount handled per day (kg ai)[3]	PHED M/L/A Dermal Unit Exposures[4] (µg ai/kg handled)	Dermal Systemic Exposure[5] (µg/kg bw/day)	Dermal MOE[6] Target 100	PHED M/L/A Inhalation Unit Exposures[4] (µg ai/kg handled)	Inhalation Systemic Exposure[5] (µg /kg bw/day)	Inhalation MOE[6] Target 100
Corn, Soybeans Dry common beans, Peanuts	farmer	0.693	150	104	53.81	80	14 900	2.56	3.8	9,740
	custom		300	208	53.81	160	7,400	2.56	7.6	4,870
Dry bulb onions	farmer	0.930	32	30	53.81	23	51 700	2.56	1.10	33 600
	custom		80	74	53.81	57	20 900	2.56	2.71	13 700
Transplanted cabbage	farmer	0.693	32	22	53.81	17	70 000	2.56	0.80	46 250
	custom		80	55	53.81	43	27 700	2.56	2.01	18,400
Established grape vines (ground directed)	farmer/ custom (ground boom)	0.624	16	10	53.81	8	148 800	2.56	0.37	100 000
	farmer/ custom (airblast)	0.624	16	10	520.41	74	16 100	7.4	1.06	35 000

[1]Maximum application rate for the crop

[2]Area treated per day from ATPD project, 2004

[3]Amount handled per day = maximum application rate *area treated per day

[4]Based on the PHED subsets for liquid open mix/load (32.77 dermal/1.6 light rate inhalation) + ground boom open cab application (21.04 dermal/0.96 light rate inhalation) or airblast application (487.64 dermal/5.8 inhalation) with coveralls over single layer of clothing plus gloves.

[5]Dermal or Inhalation Systemic Exposure (µg /kg bw/day) = [Dermal or inhalation unit exposure (µg ai/kg ai handled) *amount handled per day in kg * 100% dermal absorption]/body weight of 70 kg

[6]Dermal or inhalation MOE = Dermal NOAEL of 1190 mg/kg bw/day or inhalation NOAEL of 37 mg/kg bw/day *1000 (µg/mg) ÷ Exposure µg/kg bw/day. Target dermal/inhalation MOE is 100.

Table 6 Postapplication Exposure and Risk

Crop	Re-entry Activities	DFR[1] $\mu g/cm^2$	TC[2] (cm^2/hr)	Dermal Exposure[3] (μg/kg bw/day)	Dermal MOE[4]
corn (field, sweet or seed)	scouting, irrigation	1.39	1000	158.40	7,500
soybeans,	weeding	1.39	100	15.88	75 000
	scouting, irrigation		1500	238.29	5,000
dry common beans	hand weeding	1.39	100	15.88	75 000
	scouting and irrigation		1500	238.29	5,000
dry bulb onions	hand weeding, thinning, scouting and irrigation	1.86	300	63.77	18 660
peanuts grown in Ontario	hand weeding,	1.39	100	15.88	75 000
	scouting, irrigation		1500	238.29	5,000
transplanted cabbage (pretransplant treatment)	hand weeding	1.39	2000	317.71	3,750
	scouting, irrigation, hand harvesting, hand thinning, hand pruning		5000	794.29	1,500
established grape vines (ground directed treatment)	hand weeding, scouting	1.25	700	100	11 900
	training, thinning, hand pruning, tying, pulling		8500	1214.28	980
	handline irrigation		1100	157.14	7,570

[1]DFR = On the day of single application, 20% of application rate of 693g ai/ha (6.93 $\mu g/cm^2$), except for as 930 g ai/ha (9.3 $\mu g/cm^2$) for dry bulb onions and 624 g ai/ha
(6.24 $\mu g/cm^2$) for grapes.

[2]TC as documented in USEPA Science Advisory Council for Exposure, Policy number 003.1, 7 May 1998, revised 7August 2000. For grapes, as documented in Exposure, HED, the PMRA memo of 26 July 2005.

[3]Dermal Exposure (μg /kg bw/day) = (DFR * TC* 8 hours* 100% dermal absorption)/ body weight of 70 kg.

[4] MOE = Dermal NOAEL of 1190 mg/kg bw/day÷Exposure (μg /kg bw/day) /1000 (μg/mg); Target MOE is 100.

Table 7 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN CORN Racemic Dimethenamid	PMRA#1235253, 1131660
Radiolabeled Position	3-position of thienyl ring
Test site	Each field plot consisted of four 55 gallon metal drums, sunk into the ground and filled with loam soil.
Treatment	Single pre-emergence (soil surface) broadcast application (seeds were planted the day prior to application)
Total Rate	Either a rate of 1.68 or 4.48 kg a.i./ha (racemic dimethenamid)
End-Use Product	Formulated as a soluble concentrate (SC formulation)
Preharvest Intervals (PHIs)	Corn forage was collected at a PHI of 50 days. Immature corn (silage and grain) was collected at a PHI of 116 days. Mature corn (fodder and grain) was harvested at a PHI of 130 days.

In corn treated at the low rate, the total radioactive residues (TRRs) were 0.307 ppm in the whole plant forage, 0.403 ppm in the whole plant silage, 0.021 ppm in the immature grain, 0.504 ppm in the mature whole plant fodder and 0.022 ppm in the mature grain.

Dimethenamid was extensively metabolized in corn with approximately 30 metabolites observed. Unchanged dimethenamid was not detected in any of the corn matrices. The maximum concentration of any of the isolated metabolites was not greater than 0.05 ppm (<10% of the TRRs) in all of the matrices from the low treatment experiment. Extensive hydrolyses of the unextractable residues demonstrated that some radioactivity was incorporated into lignin, starch, proteins and cellulose.

The metabolic pathways in corn are via glutathione and/or cysteine conjugation, oxidation of the cysteine conjugate to the sulfoxide, deamination of the cysteine conjugate to the thiolactic acid conjugate and N-malonylation of the cysteine conjugate.

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Radiolabel Position	**3-Position of the Thienyl Ring**	**3-Position of the Thienyl Ring**
Corn Forage	None	Oxalamide conjugate (M23) Thiolactic acid conjugate (M26) Sulfonate conjugate (M27) Sulfoxide of the thiolactic acid conjugate (M30) Sulfoxide of the thioglycolic acid conjugate (M31) Thioglycolic acid conjugate (M32)
Corn Silage	None	M23 M26 M27 M30 M31 M32
Mature Corn Fodder	None	M23+M26 M27 M30 M31 M32
Mature Corn Grain	None	None

NATURE OF THE RESIDUE IN SOYBEAN Racemic Dimethenamid	PMRA#1124969
Radiolabel Position	3-position of thienyl ring
Test Site	Each field plot consisted of four 55 gallon metal drums, sunk into the ground and filled with loam soil.
Treatment	Single pre-emergence (soil surface) broadcast application (seeds were planted the day prior to application). The trial was conducted twice under different weather conditions, once under drought conditions (1988) and once with adequate moisture (1989).
Rate	Either a rate of 1.68 or 3.36 kg a.i./ha (racemic dimethenamid)
End-Use Product	Formulated as a soluble concentrate (SC formulation)
Preharvest Interval (PHI)	Soybean forage (whole plant) was collected at a PHI of 49 days. Soybean hay and immature seeds were collected at a PHI of 100 days. Mature soybean (seed and straw) was harvested at a PHI of 118 days.

Drought conditions (1988)
TRRs from the low/exaggerated rates were 2.158/ 3.716 ppm in the whole plant forage, 1.878/ 2.938 ppm in the whole plant hay, 0.092/ 0.196 ppm in the immature seed, 1.221/ 2.368 ppm in the straw and 0.240/ 0.473 ppm in the mature seed.

Normal conditions (1989)
TRRs from the low/exaggerated rates were 0.303/ 0.595 ppm in the whole plant forage (PHI of 42 days), 0.908/ 2.284 ppm in the whole plant hay (PHI of 100 days), 0.894/ 1.712 ppm in the straw (PHI of 128 days) and 0.131/ 0.266 ppm in the mature seed (PHI of 128 days).

Dimethenamid was extensively metabolized in soybean with approximately 30 metabolites observed. There was no evidence of dimethenamid in any soybean matrices. The maximum concentration of any of the isolated metabolites was not greater than 0.055 ppm in all of the matrices at the low treatment level. The remaining minor metabolites were at levels <0.003 ppm each. Differences in weather conditions produced differences in the magnitude of the residues, but not in the relative distribution of the TRRs in soybeans. Unextractable residues increased as a function of time post treatment.

The metabolic pathways in soybeans are via glutathione and/or cysteine conjugation, hydrolysis of the glutathione conjugate to the cysteine conjugate, oxidation of the cysteine conjugate to its sulfoxide, deamination of the cysteine conjugate to the thiolactic acid conjugate and ß-lyase cleavage plus oxidation to the sulfonate.

The following summary for each of the soybean matrices are from the 1988 trial, low application rate:

Metabolites Identified	Major Metabolites (>10% of the TRRs)	Minor Metabolites (<10% of the TRRs)
Radiolabel Position	**3-Position of the Thienyl Ring**	**3-Position of the Thienyl Ring**
Soybean forage	M23	M27 M30/M31
Soybean hay	M27	M23 M30/M31
Soybean seed	None	M23 M27 M30/M31
Soybean Straw	None	None

NATURE OF THE RESIDUE IN SUGARBEET Racemic Dimethenamid		PMRA#1281919
Radiolabel Position	3-position of thienyl ring	
Test Site	Under greenhouse conditions, 52 sugar beet seeds were planted in pots and thinned to 4 plants per pot. Following the last application, the pots containing the sugar beet plants were moved to an outdoor shed.	
Treatment	Three foliar broadcast applications (postemergence)	
Rate	Either a total rate of 1.35 or 5.40 kg a.i./ha (racemic dimethenamid)	
End-Use Product	Formulated as a soluble concentrate (SC formulation)	
Preharvest Interval (PHI)	Mature sugarbeet (roots and tops) was harvested at a PHI of 126 days.	

TRRs were 0.0783 ppm in sugar beet roots and 0.2842 ppm in sugar beet tops (lower rate; as the lower rate study was sufficient to characterize residues, samples treated at the exaggerated rate were not analyzed).

Samples were extracted sequentially with water and methanol:water (80:20, v/v), then partitioned with methylene chloride yielding organic and aqueous fractions. Extractable residues in the organic fraction were characterized and/or identified by TLC. The aqueous fraction was further cleaned up using solid-phase extraction (SPE) and characterized and/or identified by HPLC and/or TLC.

Dimethenamid was extensively metabolized as it was not found in either sugar beet roots or tops.

The metabolic pathways in sugar beets are via glutathione and/or cysteine conjugation, hydrolysis of the glutathione conjugate to the cysteine conjugate, oxidation of the cysteine conjugate to its sulfoxide, deamination of the cysteine conjugate to the thiolactic acid conjugate and N-malonylation of the cysteine conjugate.

Metabolites Identified	Major Metabolites (>10% of the TRRs)	Minor Metabolites (<10% of the TRRs)
Radiolabel Position	**3-Position of the Thienyl Ring**	**3-Position of the Thienyl Ring**
Sugarbeet roots	None	M23 M27 M28 (sulfoxide of the cysteine conjugate) M29 (N-malonylcysteine conjugate)
Sugarbeet tops	None	M27 M29 M30

NATURE OF THE RESIDUE IN CORN Comparison between Racemic Dimethenamid and Dimethenamid-P		PMRA#1377950
Radiolabeled Position	3-position of thienyl ring of dimethenamid	3-position of thienyl ring of dimethenamid-P
Test site	The study was carried out under natural climatic conditions without the influence of rain as corn plants were grown in climatic chambers in a glass-roofed vegetation hall in Germany.	
Treatment	Single postemergence application at the BBCH 13–15 growth stage (3–5 leaves unfolded) using an automatic spray track system.	
Total Rate	1300 g a.i./ha	720 g a.i./ha
End-Use Product	EC formulation BAS 656 02 H	EC formulation BAS 656 08 H
Preharvest Intervals (PHIs)	Corn forage samples were harvested at a PHI of 30 days. Immature corn forage/husks and grain/cobs were sampled at a PHI of 80 days (BBCH 83–85; early-soft dough). Mature plants were harvested at a PHI of 119 days (BBCH 89; fully ripe).	Corn forage samples were harvested at a PHI of 30 days. Immature corn forage/husks and grain/cobs were sampled at a PHI of 81 days (BBCH 83–85; early-soft dough). Mature plants were harvested at a PHI of 120 days (BBCH 89; fully ripe).

The homogenized plant samples were successively extracted with methanol and water. Due to the inhomogeneity of the samples, the total radioactive residues (TRRs) were determined by summing the extractable radioactive residues and the radioactive residues remaining after solvent extraction (the unextractable residues). The highest levels of TRRs were found in corn forage (0.718 ppm for dimethenamid-P and 2.495 ppm for racemic dimethenamid, respectively). At the second sampling, the TRRs in forage/husks accounted for 0.179 ppm for dimethenamid-P and 0.278 ppm for racemic dimethenamid, and the TRRs in grain/cobs accounted for 0.015 ppm and 0.019 ppm, respectively. At maturity, the highest TRRs were observed in straw (0.483 ppm and 0.694 ppm), whereas the TRRs in husks (0.042 ppm and 0.069 ppm), cobs (0.018 ppm and 0.028 ppm) and grain (0.026 ppm and 0.039 ppm) were considerably lower.

The nonextractable radioactive residues in the corn matrices were characterized using a sequential solubilization procedure. The results of the sequential solubilization procedures applied in both experiments indicated that parts of the TRRs after solvent extraction consisted of derivatives of dimethenamid associated with or embedded/ incorporated in insoluble natural polymers (cell wall components and starch).

Comparison of the Experiments with Dimethenamid-P and Racemic Dimethenamid:
Due to the chosen application rates, the TRRs were generally lower in the experiment with dimethenamid-P compared to racemic dimethenamid. The extractability of the radioactive residues, the partition characteristics and the results of the sequential solubilization procedure applied to the PES after solvent extraction were very similar for the two experiments. The patterns of the identified metabolites in the extracts and in the solubilizates of forage and straw and thus the metabolic pathways were qualitatively and quantitatively similar for both dimethenamid-P and racemic dimethenamid. From the experiments performed, it can be concluded that dimethenamid-P and racemic dimethenamid show a comparable behaviour in corn matrices.

Metabolic Pathways
The main metabolic pathway of dimethenamid/dimethenamid-P in plants was the formation of the glutathione conjugate (M24) and its subsequent cleavage resulting in modified cysteine conjugates (M30, M31 (or isomer), M26, M37 (or isomer)). A second metabolic route was hydrolytic/oxidative displacement of the chlorine atom, followed by glycosylation or further transformation (oxidation, N-dealkylation).

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**3-Position of the Thienyl Ring**		**3-Position of the Thienyl Ring**	
Compound	**Racemic Dimethenamid**	**Dimethenamid-P**	**Racemic Dimethenamid**	**Dimethenamid-P**
Corn forage	M30	M26 M30	M26 M31 M40 (glycosyl conjugate)	M31 M40
Corn forage/ husks	M40	M40	M23 M26 M30 M31 M37 (sulfone of the thiolactic acid conjugate) M39 (or PL1588, dealkylated amine) and one of the two isomeric metabolites, with the molecular formula $C_{11}H_{13}NO_3S$ (isomer 2)	M23 M26 M30 M31 M37 (sulfone of the thiolactic acid conjugate) M39 (or PL1588, dealkylated amine) and one of the two isomeric metabolites, with the molecular formula $C_{11}H_{13}NO_3S$ (isomer 2)
Corn grain/ cobs	None	None	M26 M30 M31 M40	M26 M30 M31 M40

Mature corn straw	M30	None	M26 M31 M40	M26 M30 M31 M40
Mature corn husks	None	None	M26 M30 M31 M40	M26 M30 M31 M40
Mature corn cobs	None	None	M30 M31 M40	M26 M30 M31 M40
Mature corn grain	None	None	M30 M31 M40	M31 M40

CONFINED ACCUMULATION IN ROTATIONAL CROPS **Racemic Dimethenamid**	**PMRA#1132367**
Radiolabel Position	3-position of the thienyl ring
Test site	Each field plot consisted of 55 gallon drums, sunk into the ground and filled with soil.
Formulation	Formulated as a soluble concentrate (SC formulation)
Application Rate and Timing	Soil treated at a rate of 1.68 kg a.i./ha for corn and soybean primary crop metabolism studies, in which mature corn and soybeans were harvested at 128 and 130 days after treatment (DAT), respectively. The confined rotational study began with planting of winter wheat at 141 DAT. Additional crops were planted the following spring at 322 DAT (spring wheat) and 332 DAT (lettuce and carrot).
Harvest of Rotational crops (Days After Planting; DAP)	Crops were harvested at maturity, 246 DAP for winter wheat, 74 DAP for spring wheat, 76 DAP for carrots and 32 DAP for lettuce. Immature wheat forage was also collected at 207 DAP for winter wheat and 42 DAP for spring wheat.

TRRs for winter wheat forage, straw and grain grown in the corn subplot were 0.0208, 0.1744 and 0.0264 ppm, respectively. Winter wheat in the soybean subplot failed to grow. TRRs for spring wheat forage, straw and grain grown in corn subplot were 0.0353, 0.1208 and 0.0196 ppm, respectively and in the soybean subplot 0.0617, 0.1417 and 0.0231 ppm, respectively. TRRs for lettuce grown in the corn subplot and soybean subplot were 0.0183 and 0.0382 ppm, respectively. TRRs for carrot roots and tops grown in corn subplot were 0.0130 and 0.0590 ppm, respectively and in the soybean subplot were 0.0130 and 0.0729 ppm, respectively.

TRRs for all rotational crop matrices were <0.18 ppm. TRRs in human consumable foods (wheat grain, carrots and lettuce) rotated on corn or soybean plots were <0.04 ppm. All extractable residues (identified and unknown) in rotational crop matrices were ≤0.010 ppm each. Dimethenamid was not detected in any matrix. Bound residues were found mostly incorporated into plant lignin and cellulose.

The metabolism of dimethenamid in secondary crops (rotational crops) is similar to the one in primary crops. As no metabolites were observed at levels higher than 0.01 ppm in the confined rotational crop study in any of the crop matrices, a field accumulation study is not triggered.

The residue definition in rotational (secondary) crops is dimethenamid, the same as the one for primary crops.

The data support a plant-back restriction of 5 months in cereals other than corn and 11 months in all other crops not listed on the Outlook label.

Metabolites Identified		Major Metabolites (>10% of the TRRs)	Minor Metabolites (<10% of the TRRs)
Matrix	**PBI (Days)**	**3-Position of the Thienyl Ring**	**3-Position of the Thienyl Ring**
Soil (0-10 cm)	0	dimethenamid	M9 M23 M31 M32
	141	dimethenamid	M9
	322	None	None
	332	None	dimethenamid
Immature winter wheat	141	None	None
Winter wheat grain	141	None	None
Winter wheat straw	141	None	M30
Immature spring wheat	322	M27	None
Spring wheat grain	322	None	None
Spring wheat straw	322	None	M30
Lettuce	332	M30	None
Carrot root	332	None	None
Carrot top	332	None	M23 M30
NATURE OF THE RESIDUE IN LAYING HEN Racemic Dimethenamid			**PMRA#1235257, 1131661**

Three laying hens were orally administered 10 mg/kg bw/day of ^{14}C-dimethenamid labeled at the 3-C thienyl position, for 4 consecutive days, equivalent to 167 ppm in the diet. Eggs and excreta were collected daily and the hens were sacrificed seven hours after the last dose.

At sacrifice, the distribution of the TRRs in the tissues was 8.3 ppm in the liver, 0.58 ppm in the leg muscle, 0.45 ppm in the breast muscle and 0.3 ppm in the fat. Residues in eggs averaged 0.6 ppm and 0.3 ppm for the yolk and albumen, respectively. The results indicated that ^{14}C was eliminated in excreta (78% of the first dose eliminated in the excreta in 24 hours).

Identification of the TRRs in the different tissues indicated that dimethenamid was the major compound in fat only (26% of the TRRs; 0.075 ppm). Overall in the tissues and fat, many metabolites were identified with none occurring at levels >10% of the TRRs. The major metabolite in eggs was identified as PL2088 and the major residue in liver was metabolite M3 (5% of the TRRs).

Based on the results of the study, it was concluded that dimethenamid was extensively metabolized in the laying hen via glutathione conjugation (M24) pathways; reductive dechlorination (M3); O-demethylation (M7 and M12); cleavage of M24 to form cysteine conjugate (M25); N-acetylation of M25 to form mercapturate conjugate (M17); dimerization of mercaptan (M22); additional metabolism of M25 to thioglycolic acid conjugate (M32), sulfonate conjugate (M27) and sulfoxide of thiolactic acid conjugate (M30); N-dealkylation to PL1588 and PL2088; S-methylation and O-demethylation of a mercaptan intermediate to M1; ring cyclization to M8; hydroxylation to M11.

Matrices	TRRs (ppm)	Percentile of Administered Dose
Excreta	Not reported	77.19
Breast muscle	0.45	0.37
Leg muscle	0.58	0.31
Fat	0.29	0.07
Liver	8.33	0.48
Egg white	0.30	0.02
Egg yolk	0.62	0.02
Total	Not reported	**78.47**
Metabolites Identified	**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Radiolabel Position	**3-Position of the Thienyl Ring**	**3-Position of the Thienyl Ring**
Excreta	M3	Dimethenamid Hydroxypropyl PL3688 PL1588 (M39) PL1688 PL2088 M1 M7 M8 M11 M12 M17 (mercapturate conjugate) M22 M25 (cysteine conjugate) M27 M30 M32
Breast muscle	None	None
Leg muscle	None	None
Fat	Dimethenamid	None
Liver	None	M3 M8
Egg white	None	PL2088
Egg yolk	None	PL2088
NATURE OF THE RESIDUE IN LACTATING GOAT Racemic Dimethenamid		**PMRA#1235252 and 1131657**

One lactating goat was orally administered 8.9 mg/kg bw/day of ^{14}C-dimethenamid labeled at the 3-C thienyl position, for four consecutive days, equivalent to 223 ppm in the diet. The goat was sacrificed seven hours after the last dosing. TRRs were determined in excreta, tissues and milk.

At sacrifice, the distribution of the total radioactive residues (TRRs) in the tissues was 16.62 ppm in the liver, 9.92 ppm in the kidney and ~1 ppm in the fat and muscle. TRRs in milk were ~0.6 ppm at the end of the dosing period. The results indicated that radioactive residues were eliminated in the excreta [68% (56% in urine and 12% in faeces) of the first dose eliminated in the excreta in 24 hours].

In an addendum to the original study, required for characterization and identification of the residues, samples from the original goat metabolism study were further analyzed; specifically, residues in kidney, liver (aqueous fraction), fat (unextractable and aqueous fractions), muscle (acetone fraction) and milk (protein/fat precipitate and unextractable fraction).

Identification of the TRRs indicated that no dimethenamid residues were present in milk, tissues or excreta. Excreta and kidney contained M3 (resulting from reductive dechlorination), M7 (resulting from the O-demethylation), M17 (mercapturate conjugate), M24 (glutathione conjugate) and M25 (cysteine conjugate); milk contained M24 and M25; muscle contained M17, M24 and M25; and fat contained M3, M7, M17 and M24.

Based on the results of the study, it was concluded that dimethenamid was completely metabolized in the lactating goat via glutathione conjugation (M24), reductive dechlorination (M3), O-demethylation (M7), cleavage of M24 to form cysteine conjugate (M25), N-acetylation of M25 to form mercapturate conjugate (M17), dimerization of mercaptan (M22) and additional metabolism.

Matrices	**TRRs (ppm)**	**Percentile of Administered Dose**
Urine	Not reported	27.26
Faeces	Not reported	8.94
Muscle	0.97	1.36
Fat	0.97	0.05
Kidney	9.92	0.08
Liver	16.62	0.75
Milk	0.51 (7 hour) 0.17 (24 hour) 0.90 (31 hour) 0.69 (48 hour) 0.98 (55 hour) 0.62 (72 hour) 0.59 (79 hour)	0.022 (total)
Metabolites Identified	**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Radiolabel Position	**3-Position of the Thienyl Ring**	**3-Position of the Thienyl Ring**
Urine	M25	M3 M7 M17 M24 M31
Faeces	M7	M3 M17 M24 M25 M31
Muscle	M17 M25	M24
Fat	M7	M17 M24 M25
Kidney	M7	M17 M24 M25
Liver	None	M17 M24 M25
Milk	M25	M17 M24

STORAGE STABILITY–Field Corn, Soybeans, Dry Bulb Onions and Cabbages Racemic Dimethenamid	PMRA#1123459, 1124973, 1293098, 1326864

Field Corn
Residues of dimethenamid are stable for 24 months and residues of the oxalamide metabolite are stable for 12 months of frozen storage at -20°C in corn matrices (forage, silage, fodder and grain).

Soybeans
Residues of dimethenamid and the sulfonate metabolite in soybean grain and forage are stable for 16 months of frozen storage at -16°C.

Dry Bulb Onions
Concurrent freezer storage data for dry bulb onions indicate that residues of dimethenamid remained stable for up to nine months at -20°C.

Cabbages
Concurrent freezer storage stability data demonstrated that residues of dimethenamid were stable for up to 216 days in cabbage under frozen conditions.

SUPERVISED FIELD TRIALS AND RESIDUE DECLINE STUDIES Field Corn Racemic Dimethenamid	PMRA#1234864, 1123456, 1148288, 1137396, 1123457, 1123458

American Trials
1989 Trials–Six field trials were conducted in the United States in North American Free Trade Agreement representative growing regions. At each test site, three application types were used: either pre-emergence, preplant incorporated or early postemergence application of dimethenemid. Two different formulations were used: a 6.0EC formulation or a 7.5L liquid formulation (applied separately at each test site) for a total of six treatment plots per test site. The single application was made by ground sprayer at a rate of 1.68 kg a.i./ha. Forage samples were collected 60 days after application, silage samples were taken approximately 135 days after application and mature corn was harvested approximately 161 days after application. All dimethenamid residues were <0.01 ppm in all the samples of corn forage, silage, grain and fodder when treated with either a 6.0EC of 7.5L formulation applied preplant, pre-emergence or early postemergence to corn at the rate of 1.68 kg a.i./ha.

1990 Trials–Five field trials were conducted in the United States in North American Free Trade Agreement representative growing regions. The 7.5L formulation was applied pre-emergence, preplant incorporated and early postemergence at each site using a single application of 1.68 kg a.i./ha using a ground sprayer. Samples of corn forage, silage, grain and fodder were collected from each plot. No residues of dimethenamid were observed in any sample from any matrix from any of the trial sites above 0.01 ppm.

1991 Trials–Six field trials were conducted in the United States in North American Free Trade Agreement growing regions using the 7.5L formulation applied: pre-emergence, preplant incorporated and early postemergence. A single application of 1.68 kg a.i./ha was made for all application types using ground spraying equipment. Samples of corn forage, silage, grain and fodder were collected. No residues of dimethenamid were observed in any sample from any matrix (n=18 for each matrix) from any of the field sites, above 0.01 ppm.

Canadian Trials
1991 Trials–Field studies were conducted at three sites in Ontario. Plots were treated with dimethenamid (7.5L formulation) at rates of 1.25 and 2.5 kg a.i./ha by ground sprayer. Treatments were preplant incorporated, preplant or postplant (five days after seeding). Corn samples were collected at 60, 90, 120 and 150 days after application. No detectable dimethenamid residues were observed in any of the corn samples in any of the trials (n=16 for each sampling at a given rate and for each site).

1992 Trials–Field trials were conducted at sites in Ontario. Plots were treated with dimethenamid (7.5L formulation) either with preplant incorporated, pre-emergence and early postemergence applications at rates of 0.75, 1.50 and 3.00 kg a.i./ha as a single ground sprayed application. Whole plant samples were taken at 60, 90 and 112 days after crop emergence. Fodder and grain were sampled 180 days after emergence. Only four out of 200 samples showed detectable amounts of 0.01 ppm dimethenamid and these were at the highest rate tested (3.0 kg a.i./ha) and the earliest sampling time (30 days after emergence).

Overall, 21 field trials were conducted in Canada and the United States in field corn. No residues (<0.01 ppm) of dimethenamid were observed in any corn sample from any matrix (forage, silage, grain and fodder) in all the field trials conducted (use rates ranging from 0.75 to 3.0 kg a.i./ha and applied either preplant, pre-emergence or early postemergence).

SUPERVISED FIELD TRIALS AND RESIDUE DECLINE STUDIES **Sweet corn** **Racemic Dimethenamid**	**PMRA#1169634**

Canadian Trials
1994 Trials–Residue trials were conducted for two varieties of sweet corn following preplant incorporation and pre-emergence treatment at 1.3 kg a.i./ha and 2.6 kg a.i./ha. Samples of kernels and fodder (remaining cobs, husks, stalks) were taken at maturity (PHIs of 58 to 84 days) and whole plant material was collected at 39-day and 53-day PHIs for pre-plant treatment and 32-day and 46-day PHIs for pre-emergence treatment.

The study was conducted at two sites (n=16 at each site) in Ontario (Zone 5). Dimethenamid residues in sweet corn treated at 1.3 and 2.6 kg a.i./ha either preplant or pre-emergence were all less than the LOQ (0.02 ppm) in whole plants (target PHIs of 30-day and 45-day) and kernels and fodder (at maturity).

SUPERVISED FIELD TRIALS AND RESIDUE DECLINE STUDIES **Soybeans** **Racemic Dimethenamid**	**PMRA#1124970, 1124971**

American Trials
1990 Trials–Five field studies were conducted in the United States in North American Free Trade Agreement representative growing regions. Plots were treated with dimethenamid at the use rate of 1.68 kg a.i./ha (7.5L formulation). Ground equipment was used to apply the formulated product pre-emergence, preplant incorporated and early postemergence. Samples of soybean forage, hay, grain and straw were collected. No residues of dimethenamid were observed in any sample from any matrix from any of the field sites, above 0.01 ppm.

1991 Trials–Seven field studies were conducted in the United States in North American Free Trade Agreement representative growing regions. Plots were treated with dimethenamid at the use rate of 1.68 kg a.i./ha (7.5L formulation). Ground equipment was used to apply the formulated product pre-emergence, preplant incorporated and early postemergence on separate plots. Samples including soybean forage, hay, grain and straw were collected. No residues of dimethenamid were observed in any sample (matrix from any of the field sites) above 0.01 ppm.

Canadian Trials
1991 and 1992 Trials–Field trials were carried out at two sites in Ontario. A single treatment of Frontier 900 EC (7.5L formulation) was applied preplant incorporated and pre-emergence at rates of 0.5, 0.75, 1.25, 1.5, 2.5 and 3.0 kg a.i./ha. Whole plant samples were taken at 30, 60 and 90 days after application. Fodder and grain were sampled 120 days after application. Only four out of eighty samples showed detectable residues of dimethenamid ranging between 0.01 - 0.02 ppm at the highest rate of 3.0 kg a.i./ha and the earliest sampling time of 30-day post-treatment. Mature grain residues of dimethenamid were <0.01 ppm even at 3.0 kg a.i./ha.

1993 Trials–Field trials were carried out in Ontario, applying Frontier 900 EC to soybeans pre-emergence at rates of 0.75, 1.5 and 3.0 kg a.i./ha. Samples (mature beans, 30 and 60 days after treatment whole plants) were collected. No residues of dimethenamid were detected in any of the samples analyzed (<0.02 ppm).

Overall, fifteen field trials were conducted in Canada and the United States in soybeans. No residues (<0.01 ppm or <0.02 ppm) of dimethenamid were observed in any soybean sample from any matrix (forage, hay, grain and straw) in all the field trials conducted (use rates ranging from 0.5 to 3.0 kg a.i./ha and applied either preplant, pre-emergence or early postemergence).

SUPERVISED FIELD TRIALS AND RESIDUE DECLINE STUDIES **Dry Common Beans** **Racemic Dimethenamid**	**PMRA#1162676**

Canadian Trials
1994 Trials–Residue trials were conducted for two varieties of white beans following preplant incorporation and pre-emergence treatment at 1.3 kg a.i./ha and 2.6 kg a.i./ha. Samples (four replicates for each rate and each application type) of white beans, pods and straw were taken at maturity and whole plant material was collected at 30 and 60 days after application. The study was conducted at two sites in Ontario.

The residue data for field samples of white beans (n=32), pods and straw (n=32) and whole plant material (n=64) indicated no detectable dimethenamid residues (<0.02 ppm), apart from one sample in one replicate plot. This sample was from the plot treated at 1.3 kg a.i./ha preplant and collected 30 days after application. The fact that it was not found in samples from the other replicate samples for that time period and at higher preplant treatment rate suggests the result to be anomalous.

SUPERVISED FIELD TRIALS AND RESIDUE DECLINE STUDIES **Dry Bulb Onions** **Racemic Dimethenamid**	**PMRA#1293098**

American Trials
1994 Trials–Eight supervised crop field trials were conducted in the United States in North American Free Trade Agreement representative growing regions on dry bulb onions treated with Frontier at a seasonal rate of 1.75 kg a.i./ha with preharvest intervals of 28–45 days. The results from these trials show that all dimethenamid residues were <0.01 ppm.

SUPERVISED FIELD TRIALS AND RESIDUE DECLINE STUDIES **Peanuts** **Racemic Dimethenamid**	**PMRA#1301842**

American Trials
1994 Trials–Fourteen supervised crop field trials were conducted in the United States in North American Free Trade Agreement representative growing regions on peanuts treated with Frontier at a seasonal rate of 1.68 kg a.i./ha, with preharvest intervals of 75–145 days. The results from these trials show that all dimethenamid residues were <0.01 ppm.

SUPERVISED FIELD TRIALS AND RESIDUE DECLINE STUDIES **Cabbage transplants** **Racemic Dimethenamid**	**PMRA#1326864**

Canadian Trials
2003 and 2004 Trials–Five supervised crop field trials were conducted in Canada in North American Free Trade Agreement representative growing regions on cabbages treated with Frontier at a seasonal rate of 1.26 kg a.i./ha, with preharvest intervals of 58–77 days. The results from these trials show that all dimethenamid residues were <0.01 ppm.

PROCESSED FOOD AND FEED–Corn, Soybeans and Peanuts Racemic Dimethenamid	PMRA#1234862, 1123460, 1124972 and 1301843

Field Corn–Fractions analyzed for dry milled processing included grain dust, grits, meal, flour, hulls, solvent extracted presscake, crude and refined oil, soapstock, refined bleached oil, refined bleached deodorized oil and deodorized distillates. Fractions from wet milled processing included coarse gluten starch, gluten, starch, process water, hulls, solvent extracted presscake, crude oil, refined oil, soapstock, refined bleached oil, refined bleached deodorized oil and deodorized distillates.

The dimethenamid residues were not quantifiable in corn samples (grain or processed fractions) treated at the 5x rate. Therefore, since no residues above 0.01 ppm were found, no concentration factor can be calculated. However, it can be concluded that there is no concentration of dimethenamid residues in corn fractions upon processing when treated up to five times the registered rate for dimethenamid.

Soybeans–Processed fractions included: hulls, solvent extracted meal, crude oil, degummed oil, crude lecithin, refined oil, soapstock and refined bleached oil.

The dimethenamid residues were not quantifiable in soybean samples (seed or processed fractions) treated at the 5x rate. Therefore, since no residues above 0.01 ppm were found, no concentration factor can be calculated. However, it can be concluded that there is no concentration of dimethenamid residues in soybean fractions upon processing when treated up to five times the registered rate for dimethenamid.

Peanuts–The dimethenamid residues were not quantifiable in peanut nutmeat samples (seed) treated at the 5x rate. Therefore, since no residues above 0.01 ppm were found, peanuts were not submitted for processing.

LIVESTOCK FEEDING

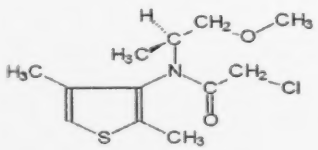
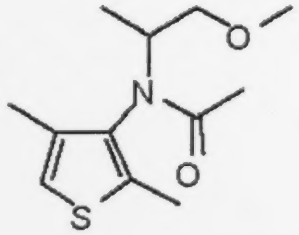
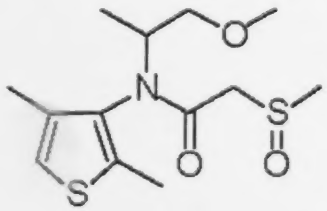
Based on the results from the livestock metabolism studies (corresponding to >5700-fold the MTDB in beef and >1390-fold the MTDB in poultry), dimethenamid was not detected in any animal tissues (except poultry fat), milk and egg and no predominant metabolites (>10% of the TRRs) were observed in any matrices.

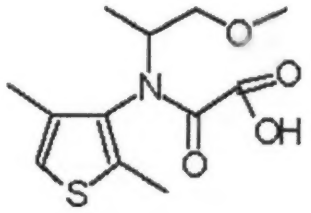
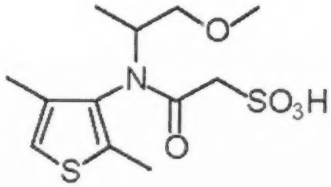
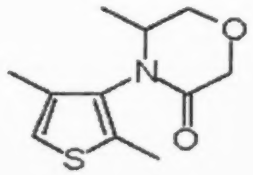
As no finite residues are expected in animal matrices based on the currently registered feed items and dietary burdens, livestock feeding studies are not required at this time.

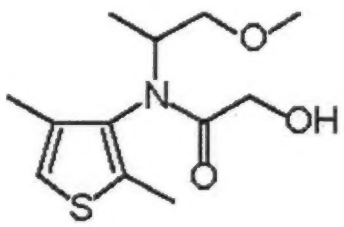
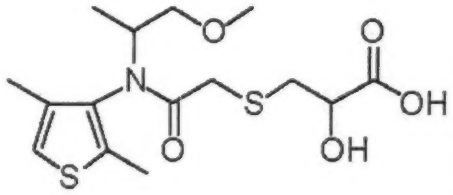
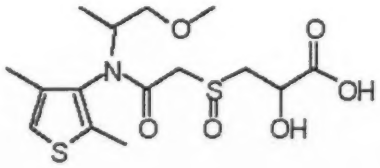
Table 8 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES			
RESIDUE DEFINITION FOR ENFORCEMENT AND RISK ASSESSMENT **Primary and Secondary Crops**	Dimethenamid		
METABOLIC PROFILE IN DIVERSE CROPS	Metabolism in three diverse crops (field corn, soybeans and sugarbeet) was investigated.		
ANIMAL STUDIES			
ANIMALS	**Poultry and Ruminant**		
RESIDUE DEFINITION FOR ENFORCEMENT AND RISK ASSESSMENT **Poultry Commodities** **Ruminant Commodities**	Dimethenamid Dimethenamid and the metabolites M7, M17 and M25		
METABOLIC PROFILE IN ANIMALS	Similar metabolic profile was observed in rat, hen and goat.		
FAT SOLUBLE RESIDUE	No		
DIETARY RISK FROM FOOD AND WATER			
	POPULATION	**ESTIMATED RISK Percentile of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Only	**Food and Water**
Basic Chronic Non-Cancer Dietary Risk **ADI = 0.05 mg/kg bw/day** **Estimated Chronic Drinking Water Concentration = 23 µg a.i./L**	**All infants < 1 year**	3.0	6.2
	Children 1–2 years	8.7	10.1
	Children 3–5 years	5.9	7.3
	Children 6–12 years	3.6	4.5
	Youth 13–19 years	1.7	2.4
	Adults 20–49 years	1.2	2.1
	Adults 50+ years	1.1	2.0
	Female 13–49 years	1.2	2.1
	Total population	1.9	2.9

Table 9 Fate and Behaviour in the Environment

Code	Chemical Name	Chemical Structure	Study	Max% AR	Day Max Reached	Study Duration (d)
PARENT						
	2-chloro-N-(2,4-dimethyl-3thienyl)-N-[(1 S)-2-methoxy-1-methylethyl]-acetamide					
MAJOR (>10%) TRANSFORMATION PRODUCTS						
M3	N-(2,4-dimethyl-3-thienyl)-N(2-methoxy-1-methylethyl)acetamide		Aerobic soil			
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis	0.31	16	31
			Hydrolysis			
			Aerobic aquatic	14.3	105	105
			Anaerobic aquatic	20.6	90	360
			Field studies			
			Other			
M13	N-(2,4-dimethyl-3-thienyl)-N(2-methoxy-1-methylethyl)-2-(methylsulfinyl)acetamide		Aerobic soil			
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic	<7		105
			Anaerobic aquatic	12.4	120	360
			Field studies			
			Other			

Code	Chemical Name	Chemical Structure	Study	Max% AR	Day Max Reached	Study Duration (d)
M23 oxalamide	N-(2,4-dimethyl-3-thienyl)-N(2-methoxy-1-methylethyl)oxalamic acid		Aerobic soil	14.8	90	365
			Anaerobic soil	8.7	93	93
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic	<7		105
			Anaerobic aquatic			
			Field studies	detected		
			Other			
M27 sulfonate	2-[N-(2,4-dimethyl-3-thienyl)N- (2-methoxy-1-methylethyl)amino]-2-oxoethylsulfonic acid		Aerobic soil	10-13	unknown	
			Anaerobic soil	3.5	93	93
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			
			Field studies			
			Other			
MINOR (<10%) TRANSFORMATION PRODUCTS						
M9	4-(2,4-dimethyl-3-thienyl)-5-methyl-3-morpholinone		Aerobic soil			
			Anaerobic soil			
			Soil photolysis			
			Aqueous	0.82	16	16
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			
			Field studies			
			Other			

M11	N-(2,4-dimethyl-3-thienyl)-2hydroxy-N-(2-methoxy-1-methylethyl)acetamide		Aerobic soil	<5		182
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis	1.8		16
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			
			Field studies			
			Other			
M26 thiolactic acid conj.	2-[N-(2,4-dimethyl-3-thienyl)N-(2-methoxy-1-methylethyl)amino]-2-oxoethylthiolactic acid		Aerobic soil	<5		182
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			
			Field studies			
			Other			
M30 sulfoxide of thiolactic acid conj.	sulfoxide of 2-[N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)amino]2-oxoethyl thiolactic acid		Aerobic soil	<5		182
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			
			Field studies			
			Other			

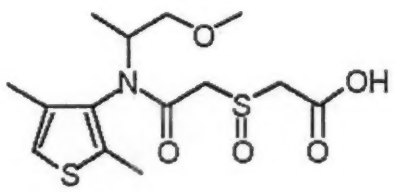
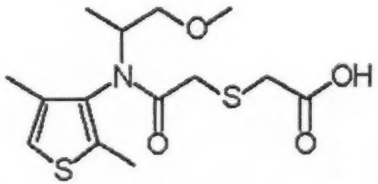
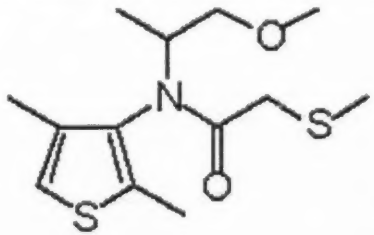
M31 sulfoxide of thioglycolic acid conj.	sulfoxide of 2-[N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)amino]2-oxoethyl thioglycolic acid		Aerobic soil	7		182
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic	<7		105
			Anaerobic aquatic			
			Field studies			
			Other			
M32 thioglycolic acid conj.	sulfoxide of 2-[N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)amino]2-oxoethyl thioglycolic acid		Aerobic soil	<5		182
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			
			Field studies			
			Other			
PL36-88	N-(2,4-dimethyl-3-thienyl)-N(2-methoxy-1-methylethyl)-2-methylthioacetamide		Aerobic soil			
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic	<7		105
			Anaerobic aquatic			
			Field studies			
			Other			

Table 9.1 Fate and Behaviour of Dimethenamid-P in the Terrestrial Environment

Property	Test Substance	Value	Transformation Products	Comments	PMRA#
Abiotic Transformation					
Hydrolysis	Dimethenamid-P	Stable		Not an important route of transformation	1044833
Phototransformation on soil	Dimethenamid-P	DT_{50}: 37.5 days	Region 1, 3, 4, 5 (M7, M9, M11, M20)	Not an important route of transformation	1044814 1044840
Phototransformation in water	Dimethenamid-P	Half-life: 16 days	M3, M9 M11	Not an important route of transformation	1079034 1044816
Phototransformation in air	N/A			Data not required	
Biotransformation					
Biotransformation in aerobic soil	Dimethenamid-P	DT_{50}: 7.8 days	M11, M23, M26, M27, M30, M32	Non-persistent	1062566 1044818 1235272
Biotransformation in anaerobic soil	Dimethenamid	DT_{50}: 59 days	M23, M27	Moderately persistent	1235273
Biotransformation in aerobic water/sedment	Dimethenamid	DT_{50}: 11-37 days	M3, M13, M23, M31, PL36-88	Slightly persistent	1079024
Biotransformation in anaerobic water	Dimethenamid	DT_{50}: 35 days	M3, M13	Slightly persistent	1131636
Mobility					
Adsorption / desorption in soil	Dimethenamid-P	K_{oc} (adsorption): 90-474 K_{oc} (desorption): 110-609		Moderately to highly mobile	1044834 1044835
	M23	K_{oc} (adsorption): 3.5-17.2		Very highly mobile	1079025 1079026
	M27	K_{oc} (adsorption): 0-14.4		Very highly mobile	1079025 1079026
Soil leaching	Dimethenamid	TLC R_f : loam soil: 0.21 clay loam: 0.21 sandy loam: 0.48		Low to intermediate mobility	1238623

Property	Test Substance	Value	Transformation Products	Comments	PMRA#
	M23	TLC R_f : loam soil: 0.69 clay loam: 0.64 sandy loam: 0.84		Mobile	1238623
Volatilization	Dimethenamid-P	24-hour volatilization: from soil: 6.6% from plant surface: 14.1%			1079027
Field Studies					
Field dissipation	Dimethenamid	DT_{50}: 7.1-43 days	M23	Non to slightly persistent	1128682
Field leaching	Dimethenamid	Reached maximum depth of 30 cm.	M23 was not detected below 15 cm in six studies, but was detected between 20-30 cm in one study		1128682

Table 9.2 Fate and Behaviour of Dimethenamid-P in the Aquatic Environment

Study Type	Test Material	Value	Transformation Products	Comments	PMRA#
Abiotic Transformation					
Hydrolysis	Dimethenamid-P	Stable		Not an important route of transformation	1044833
Phototransformation in water	Dimethenamid-P	Half-life: 16 days	M3, M9 M11	Not an important route of transformation	1079034, 1044816
Biotransformation					
Biotransformation in aerobic water/sediment	Dimethenamid	Half-life: 20-37 days	M3, M13, M23, M31, PL36-88	Slightly persistent	1079024
Biotransformation in anaerobic water/sediment system	Dimethenamid	Half-life: 35 days	M3, M13	Slightly persistent	1031636

Toxicity to Non-Target Species

Table 10.1 Toxicity Effects of Dimethenamid-P to Terrestrial Organisms

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity[a]	PMRA#
Invertebrates					
Earthworm	Acute	Dimethenamid	LC_{50}: 250 (mg a.i./kg soil)		1450503 1079034 1235329
		M23	LC_{50}: >1264 (mg/kg soil)		1079034
		M27	LC_{50}: >1264 (mg/kg soil)		1079034
Bee	Oral	Dimethenamid	LD_{50}: >1000 µg a.i./bee	Relatively non-toxic	1235328
	Contact	Dimethenamid	LD_{50}: 94 ug a.i./bee	Relatively non-toxic	1235328
Birds					
Bobwhite quail	Acute	Dimethenamid-P	LD_{50}:1068 mg a.i./kg bw NOEC (bd weight): <292 mg a.i /kg bw	Slightly toxic	1044860
	Dietary	Dimethenamid-P	LC_{50}:>5620 mg ai /kg NOEC (food consumption): 1780 mg ai /kg	Practically non-toxic	1044862
	Reproduction	Dimethenamid	NOEC (egg shell thickness): 900 mg a.i./kg		1079034 1079029 1079030
Mallard duck	Dietary	Dimethenamid-P	LC_{50}:>5620 mg ai /kg NOEC (food consumption): 1780 mg ai /kg	Practically non-toxic	1044863
	Reproduction	Dimethenamid	NOEC (egg shell thickness): 1800 mg a.i./kg		1079034 1079031 1079032

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity[a]	PMRA#
Mammals					
Rat	Acute	Dimethenamid-P	LD_{50}: 466 mg a.i./kg	Highly toxic	1128684
		Outlook	LD_{50}: 695 mg a.i./kg	Moderately toxic	1090482
	Dietary	Dimethenamid-P	NOEC: 37 mg/kg bw/d		1128693
	Reproduction	Dimethenamid	Parental: NOAEL: 25.0 mg/kg bw/d Decreased food consumption and body weight of parental males in both generations. Reproductive: NOAEL: 34.0 mg/kg bw/d Decreased body weights of pups during lactation.		
	Developmental toxicity	Dimethenamid-P	Maternal: NOAEL: 25 mg/kg bw/d LOAEL: 150 mg/kg bw/d Clinical effects, decreased body weight and food consumption Developmental: NOAEL: 300 mg/kg bw/d LOAEL: Not determined		1128694
Vascular Plants					
Vascular plant (Perennial ryegrss)	Seedling emergence	Dimethenamid-P	EC_{25}: 7.7 g a.i./ha NOEC: 2.8 g a.i./ha		1128719 1044837
	Vegetative vigour		EC_{25}: 26 g a.i./ha NOEC: 12.3 g a.i./ha		1128719 1044837

[a] Atkins *et al.* (1981) for bees and USEPA classification for others, where applicable

Table 10.2 Toxicity Effects of Dimethenamid-P to Aquatic Organisms

Organism (Species)	Exposure	Test Substance	Endpoint Value	Degree of Toxicity[a]	PMRA#
Freshwater Species					
Daphnia magna	Acute	Dimethenamid-P	LC_{50}: 12 mg a.i./L	Slightly toxic	1044847
	Chronic	Dimethenamid-P [b]	NOEC: 1.02 mg a.i./L		1128682 1044837
Rainbow trout	Acute	Dimethenamid-P	LC_{50}: 6.3 mg a.i./L NOEC: 3.7 mg a.i./L	Moderately toxic	1044852
	Early life-stage	Dimethenamid-P [b]	NOEC: 0.3 mg a.i./L		1044837
Bluegill sunfish	Acute	Dimethenamid-P	LC_{50}: 10 mg a.i./L NOEC(behaviour): 4.1 mg a.i./L	Moderately toxic	1044854
Freshwater algae (Green algae)	Acute	Dimethenamid-P	EC_{50}: 0.017 mg a.i./L		1128715 1128716 1128717
Vascular plants (Duckweed)	Dissolved	Dimethenamid-P	EC_{50} (biomass): 0.0089 mg a.i./L		1128720
Marine Species					
Invertebrates (Saltwater mysid)	Acute	Dimethenamid-P	LC_{50}: 3.2 mg a.i./L NOEC(behaviour): 1.2 mg a.i./L	Moderately toxic	1044849
Fish (Sheepshead minnow)	Acute	Dimethenamid-P	LC_{50}: 12 mg a.i./L NOEC (behaviour): 5.3 mg a.i./L	Slightly toxic	1044856
Marine algae (Marine diatom)	Acute	Dimethenamid-P	EC_{50}: 0.12 mg a.i./L NOEC: 0.03 mg a.i./L		1128718

[a]USEPA classification, where applicable
[b]USEPA estimation from the racemic diemthenamid data

Table 11.1 Risks of Dimethenamid-P to Terrestrial Invertebrates and Plants

Organism	Exposure	Endpoint	Endpoint Value	Uncertainty Factor	EEC[2] (mg a.i./kg dw)	Unit	RQ[3]	LOC[4] Exceeded
Invertebrates								
Earthworm	Acute	LC_{50}	250	2	0.41	mg a.i./kg dw	0.003	N
Bee[1]	Oral	LC_{50}	>1120	1	0.93	kg a.i./ha	<0.001	N
	Contact	LC_{50}	105.3	1	0.93	kg a.i./ha	0.009	N
Vascular Plants								
Most sensitive species of ten tested (Ryegrass)	Seedling emergence	EC_{25}	7.7	1	930	g a.i./ha	120.79	Y
		EC_{25}	7.7	1	55.8[5] off-field assessment	g a.i./ha	7.25	Y
		HC_5	13.7	1	55.8[5] off-field assessment	g a.i./ha	4.07	Y
	Vegetative vigour	EC_{25}	26	1	930	g a.i.//ha	35.77	Y
		EC_{25}	26	1	55.8[5] off-field assessment	g a.i.//ha	2.15	Y

1. Toxicity in µg/bee was converted to the equivalent kg a.i./ha using a conversion factor of 1.12 (Atkins et al., 1981).
2. Environmental exposure concentration (EEC). It is calculated with the maximum seasonal rate (930 g a.i./ha) proposed for registration in Canada; Off-field EEC is estimated using spray drift rate of 6% of the maximum application rate (ASAE, medium droplet), when the RQ exceeded the LOC. EEC is calculated using the PMRA standard methods based on the Hoerger and Kenaga nomogram as modified by Fletcher (1994).
3. Risk Quotient (RQ) = EEC/(Endpoint values /uncertainty factor).
4. Level of Concern (LOC=1); Y indicates that LOC is exceeded; N indicates that LOC is not exceeded.
5. Refined risk assessment is conducted for spray drift scenarios when initial RQ exceeded the LOC. The EEC for off-field is estimated using spray drift rate of 6% of the maximum application rate (ASAE, medium droplet).

Table 11.2 Risks of Dimethenamid-P to Birds and Mammals

Organism	FIR[1] (g dw/day)	Exposure	Endpoint[2]	Endpoint Value	Uncertainty Factor	Feeding Guild	Matrix	EEC[3] (mg a.i./kg dw)	EDE[4] (mg a.i./kg bw/day)	RQ[5]	LOC[6] Exceeded
20 g bird	5.078	Acute	LD_{50}	1068	10	Insectivore	Small insects	183.77	46.66	0.44	N
				1068	10	Granivore	Grain and seeds	31.45	7.99	0.07	N
				1068	10	Frugivore	Fruit	94.71	24.05	0.23	N
		Dietary	LD_{50}	>596.73	10	Insectivore	Small insects	183.77	46.66	<0.78	N
				>596.73	10	Granivore	Grain and seeds	31.45	7.99	<0.14	N
				>596.73	10	Frugivore	Fruit	94.71	24.05	<0.40	N
		Reproduction	NOEC	95.96	1	Insectivore	Small insects	183.77	46.66	0.49	N
				95.96	1	Granivore	Grain and seeds	31.45	7.99	0.08	N
				95.96	1	Frugivore	Fruit	94.71	4.81	0.25	N
100 g bird	19.95	Acute	LD_{50}	1068	10	Insectivore	Small insects	183.77	36.66	0.34	N
				1068	10	Granivore	Grain and seeds	31.45	6.27	0.06	N
				1068	10	Frugivore	Fruit	94.71	18.89	0.18	N
		Dietary	LD_{50}	>596.73	10	Insectivore	Small insects	183.77	36.66	<0.61	N
				>596.73	10	Granivore	Grain and seeds	31.45	6.27	<0.10	N
				>596.73	10	Frugivore	Fruit	94.71	18.89	<0.32	N

Organism	FIR[1] (g dw/day)	Exposure	Endpoint[2]	Endpoint Value	Uncertainty Factor	Feeding Guild	Matrix	EEC[3] (mg a.i./kg dw)	EDE[4] (mg a.i./kg bw/day)	RQ[5]	LOC[6] Exceeded
		Reproduction	NOEC	95.96	1	Insectivore	Small insects	183.77	36.66	0.38	N
				95.96	1	Granivore	Grain and seeds	31.45	6.27	0.07	N
				95.96	1	Frugivore	Fruit	94.71	1.89	0.20	N
1000 g bird	58.12	Acute	LD_{50}	1068	10	Insectivore	Small insects	183.77	10.68	0.10	N
				1068	10	Granivore	Grain and seeds	31.45	1.83	0.02	N
				1068	10	Frugivore	Fruit	94.71	5.50	0.05	N
				1068	10	Herbivore	Leaves, leafy crops	1145.76	66.59	0.62	N
		Dietary	LD_{50}	>596.73	10	Insectivore	Small insects	183.77	10.68	<0.18	N
				>596.73	10	Granivore	Grain and seeds	31.45	1.83	<0.03	N
				>596.73	10	Frugivore	Fruit	94.71	5.50	<0.09	N
				>596.73	10	Herbivore	Leaves, leafy crops	1145.76	66.59	<1.11	Y
				>596.73	10	Herbivore Off-field[7] assessment	Leaves, leafy crops	68.75	4.00	<0.07	N
		Reproduction	NOEC	95.96	1	Insectivore	Small insects	183.77	10.68	0.11	N
				95.96	1	Granivore	Grain and seeds	31.45	1.83	0.02	N
				95.96	1	Frugivore	Fruit	94.71	5.50	0.06	N
				95.96	1	Herbivore	Leaves, leafy crops	1145.76	66.59	0.69	N

Organism	FIR[1] (g dw/day)	Exposure	Endpoint[2]	Endpoint Value	Uncertainty Factor	Feeding Guild	Matrix	EEC[3] (mg a.i./kg dw)	EDE[4] (mg a.i./kg bw/day)	RQ[5]	LOC[6] Exceeded
15 g mammal	2.18	Acute	LD_{50}	466	10	Insectivore	Small insects	183.77	26.71	0.57	N
				466	10	Granivore	Grain and seeds	31.45	4.57	0.10	N
				466	10	Frugivore	Fruit	94.71	13.76	0.30	N
		Dietary	NOEC	37	1	Insectivore	Small insects	183.77	26.71	0.72	N
				37	1	Granivore	Grain and seeds	31.45	4.57	0.12	N
				37	1	Frugivore	Fruit	94.71	13.76	0.37	N
		Reproduction	NOEC	25	1	Insectivore	Small insects	183.77	26.71	1.07	Y
				25	1	Insectivore Off-field[7] assessment	Small insects	11.03	1.6	0.06	N
				25	1	Granivore	Grain and seeds	31.45	4.57	0.18	N
				25	1	Frugivore	Fruit	94.71	13.76	0.55	N
35 g mammal	4.37	Acute	LD_{50}	466	10	Insectivore	Small insects	183.77	22.94	0.49	N
				466	10	Granivore	Grain and seeds	31.45	3.93	0.08	N
				466	10	Frugivore	Fruit	94.71	11.83	0.25	N
				466	10	Herbivore	Leaves, leafy crops	1145.76	143.06	3.07	Y
				466	10	Herbivore Off-field[7] assessment	Leaves, leafy crops	68.75	8.58	0.18	N

Organism	FIR[1] (g dw/day)	Exposure	Endpoint[2]	Endpoint Value	Uncertainty Factor	Feeding Guild	Matrix	EEC[3] (mg a.i./kg dw)	EDE[4] (mg a.i./kg bw/day)	RQ[5]	LOC[6] Exceeded
		Dietary	LD_{50}	37	10	Insectivore	Small insects	183.77	22.94	6.20	Y
				37	10	Insectivore Off-field[7] assessment	Small insects	11.026	1.38	0.37	N
				37	10	Granivore	Grain and seeds	31.45	3.93	1.06	Y
				37	10	Granivore Off-field[7] assessment	Grain and seeds	1.887	0.24	0.06	N
				37	10	Frugivore	Fruit	94.71	11.83	3.20	Y
				37	10	Frugivore Off-field[7] assessment	Fruit	5.6827	0.71	0.19	N
				37	10	Herbivore	Leaves, leafy crops	1145.76	143.06	38.66	Y
				37	10	Herbivore Off-field[7] assessment	Leaves, leafy crops	68.745	8.58	2.32	Y
				37	10	Herbivore	Short range grass	656.78	82.00	22.16	Y
				37	10	Herbivore Off-field[7] assessment	Short range grass	39.41	4.92	1.33	Y
		Reproduction	NOEC	25	1	Insectivore	Small insects	183.77	22.94	0.92	N
				25	1	Granivore	Grain and seeds	31.45	3.93	0.16	N
				25	1	Frugivore	Fruit	94.71	11.83	0.47	N
				25	1	Herbivore	Leaves, leafy crops	1145.76	143.06	5.72	Y

Organism	FIR[1] (g dw/day)	Exposure	Endpoint[2]	Endpoint Value	Uncertainty Factor	Feeding Guild	Matrix	EEC[3] (mg a.i./kg dw)	EDE[4] (mg a.i./kg bw/day)	RQ[5]	LOC[6] Exceeded
				25	1	Herbivore Off-field[7] assessment	Leaves, leafy crops	68.75	8.58	0.34	N
1000 g mammal	68.72	Acute	LD_{50}	466	10	Insectivore	Small insects	183.77	12.63	0.27	N
				466	10	Granivore	Grain and seeds	31.45	2.16	0.05	N
				466	10	Frugivore	Fruit	94.71	6.51	0.14	N
				466	10	Herbivore	Leaves, leafy crops	1145.76	78.74	1.69	Y
				466	10	Herbivore Off-field[7] assessment	Leaves, leafy crops	68.745	4.72	0.10	N
		Dietary	LD_{50}	37	10	Insectivore	Small insects	183.77	12.63	3.41	Y
				37	10	Insectivore Off-field[7] assessment	Small insects	11.026	0.76	0.20	N
				37	10	Granivore	Grain and seeds	31.45	2.16	0.58	N
				37	10	Frugivore	Fruit	94.71	6.51	1.76	Y
				37	10	Frugivore Off-field[7] assessment	Fruit	5.6827	0.39	0.11	N
				37	10	Herbivore	Leaves, leafy crops	1145.76	78.74	21.28	Y
				37	10	Herbivore Off-field[7] assessment	Leaves, leafy crops	68.745	4.72	1.28	Y

Organism	FIR[1] (g dw/day)	Exposure	Endpoint[2]	Endpoint Value	Uncertainty Factor	Feeding Guild	Matrix	EEC[3] (mg a.i./kg dw)	EDE[4] (mg a.i./kg bw/day)	RQ[5]	LOC[6] Exceeded
				37	10	Herbivore	Short range grass	656.78	45.13	12.20	Y
				37	10	Herbivore Off-field[7] assessment	Short range grass	39.41	2.71	0.73	N
		Reproduction	NOEC	25	1	Insectivore	Small insects	183.77	12.63	0.51	N
				25	1	Granivore	Grain and seeds	31.45	2.16	0.09	N
				25	1	Frugivore	Fruit	94.71	6.51	0.26	N
				25	1	Herbivore	Leaves, leafy crops	1145.76	78.74	3.15	Y
				25	1	Herbivore Off-field[7] assessment	Leaves, leafy crops	68.75	4.72	0.19	N

1. Food ingestion rate. FIR was based on equations from Nagy (1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used; for mammals, the "all mammals" equation was used.
   Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
   All Birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$
   All Mammals Equation: FIR (g dry weight/day) = 0.235(BW in g) $^{0.822}$
2. Bird dietary LD_{50} valued were conversed from LC_{50} from submitted studies [D_{50} (mg a.i./kg bw) = LC_{50} (mg a.i./kg diet)/BW (g) x FIR (g diet/day)]
3. Environmental exposure concentration (EEC). It is calculated with the maximum seasonal rate (930 g a.i./ha) proposed for registration in Canada; Off-field EEC is estimated using spray drift rate of 6% of the maximum application rate (ASAE, medium droplet), when the RQ exceeded the LOC. EEC is calculated using PMRA standard methods based on the Hoerger and Kenaga nomogram as modified by Fletcher (1994).
4. Estimated dietary exposure (EDE). For birds and mammals, the EEC was converted into EDE with the maximum application rate or 6% spray drift adjusted rate on appropriate food item for each food guild. The EDE was calculated using the following formula: (FIR/BW) x EEC.
5. Risk Quotient (RQ) = EEC/(Endpoint values /uncertainty factor).
6. Level of Concern (LOC=1); Y indicates that LOC is exceeded; N indicates that LOC is not exceeded.
7. Refined risk assessment is conducted for spray drift scenarios when initial RQ exceeded the LOC. The EEC for off-field is estimated using spray drift rate of 6% of the maximum application rate (ASAE, medium droplet).

Table 11.3 Risk of Dimethenamid-P to Aquatic Organisms

Organism	Exposure	Substance	Endpoint	Endpoint Value (mg a.i./L)	Uncertainty Factor	EEC[1] (mg a.i./L)	RQ[2]	LOC[3] Exceeded
Freshwater Species								
Daphnia magna	Acute	Dimethenamid-P	LC_{50}	12	2	0.12	0.02	N
	Chronic	Dimethenamid-P[4]	NOEC	1.02	1	0.12	0.12	N
Rainbow trout	Acute	Dimethenamid-P	LC_{50}	6.3	10	0.12	0.19	N
	Early life-stage	Dimethenamid-P[4]	NOEC	0.3	1	0.12	0.4	N
Bluegill sunfish	Acute	Dimethenamid-P	LC_{50}	10	10	0.12	0.12	N
Amphibian[5]	Acute	Dimethenamid-P	LC_{50}	6.3	10	0.62	0.98	N
	Early life-stage	Dimethenamid-P[4]	NOEC	0.3	1	0.62	2.07	Y
	Early life-stage (runoff[6] assessment)	Dimethenamid-P[4]	NOEC	0.3	1	0.17	0.57	N
	Early life-stage (off-field[7] assessment)	Dimethenamid-P[4]	NOEC	0.3	1	0.037	0.127	N
Freshwater algae (Green Algae)	Acute	Dimethenamid-P	EC_{50}	0.017	2	0.12	14.12	Y
	Acute (Runoff[6] assessment)	Dimethenamid-P	EC_{50}	0.017	2	0.035	2.06	Y
	Acute (Off-field[7] assessment)	Dimethenamid-P	EC_{50}	0.017	2	0.007	0.82	N
Vascular plants (Duckweed)	Dissolved	Dimethenamid-P	EC_{50}	0.0089	2	0.12	26.97	Y
	Dissolved (Runoff[6] assessment)	Dimethenamid-P	EC_{50}	0.0089	2	0.035	7.87	Y

Organism	Exposure	Substance	Endpoint	Endpoint Value (mg a.i./L)	Uncertainty Factor	EEC[1] (mg a.i./L)	RQ[2]	LOC[3] Exceeded
	Dissolved (Off-field[7] assessment)	Dimethenamid-P	EC_{50}	0.0089	2	0.007	1.57	Y
Marine Species								
Invertebrates (Saltwater mysid)	Acute	Dimethenamid-P	LC_{50}	3.2	2	0.12	0.08	N
Fish (Sheepshead minnow)	Acute	Dimethenamid-P	LC_{50}	12	10	0.12	0.1	N
Marine algae (Marine diatom)	Acute	Dimethenamid-P	EC_{50}	0.12	2	0.12	2.0	Y
	Acute (Runoff[6] assessment)	Dimethenamid-P	EC_{50}	0.12	2	0.035	0.58	N
	Acute(Off-field[7] assessment)	Dimethenamid-P	EC_{50}	0.12	2	0.007	0.12	N

1. Environmental Exposure Concentration (EEC). It is calculated with the maximum seasonal rate (930 g a.i./ha) proposed for registration in Canada; The EEC for off-field is estimated using spray drift rate of 6% of the maximum application rate (ASAE, medium droplet),; The EEC for runoff is the maximum EEC concentration estimated with PRZM/EXAMS runoff models.
2. Risk Quotient (RQ) = EEC/ (Endpoint values /uncertainty factor).
3. Level of Concern (LOC=1); Y indicates that LOC is exceeded; N indicates that LOC is not exceeded.
4. USEPA estimation from the racemic dimethenamid data.
5. Amphibian endpoint values are based on fish toxicity data.
6. Refined risk assessment is conducted for runoff ecoscenarios when initial RQ exceeded the LOC. The EEC for runoff is the maximum EEC concentration estimated with PRZM/EXAMS runoff models.
7. Refined risk assessment is conducted for spray drift scenarios when initial RQ exceeded the LOC. The EEC for off-field is estimated using spray drift rate of 6% of the maximum application rate (ASAE, medium droplet).

Table 11.4 Buffer Zone Calculated for Dimethenamid-P

Method of Application	Crop	Buffer Zones (Metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial Habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Corn, soybean, beans, onion, cabbage, peanuts and grapes	1	1	1	0	3

*For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

Table 12 Alternative Herbicides for Weed Control in Crops Labeled for Frontier Max Herbicide

Technical Grade Active Ingredient	End-Use Product(s)	Crop Claims	Weed Claims	Herbicide Classification	
				Group	Mode of Action
nicosulfuron	Accent	Field and sweet corn	Annual grasses plus quackgrass	2	ALS inhibitor
rimsulfuron	Elim	Field corn	Annual grasses plus lamb's-quarters and redroot pigweed	2	ALS inhibitor
nicosulfuron + rimsulfuron	Ultim	Field corn	Annual grasses plus quackgrass and redroot pigweed	2	ALS inhibitor
s-metolachlor	Dual II Magnum	Corn, soybean, cabbage and dry beans.	Annual grasses and certain broadleaf weeds	15	Inhibition of cell division (VLCFA inhibition)
EPTC	Eradicane, Eptam	Corn and beans	Grassy and broadleaf weeds	8	Inhibition of lipid synthesis
flufenacet	Flufenacet	Field corn	Green foxtail, redroot pigweed and lamb's-quarters	15	Inhibition of cell division (VLCFA inhibition)
atrazine	Aatrex Liquid	Corn	Broadleaf weeds and wild oats	5	Inhibitors of photosynthesis at photosystem II Site A
trifluralin	Rival	Soybeans, cabbage and beans	Annual grasses and broadleaf weeds	3	Microtubule assembly inhibition

Technical Grade Active Ingredient	End-Use Product(s)	Crop Claims	Weed Claims	Herbicide Classification	
				Group	Mode of Action
imazethapyr	Pursuit	Soybeans and dry common beans	Annual grasses and broadleaf weeds	2	ALS inhibitor
pendimethalin	Prowl	Field corn and dry bulb onions	Annual grasses and broadleaf weeds	3	Microtubule assembly inhibition
topramezone	Impact	Field corn	Broadleaf weeds and grasses	27	HPPD inhibition
linuron	Lorox	Field and sweet corn, soybeans,	Annual grasses and broadleaf weeds	7	Inhibition of photosynthesis at photosystem II
isoxaflutole	Converge Pro	Field corn	Annual grasses and broadleaf weeds	27	HPPD inhibition
simazine	Princep Nine-T	Corn, grapes,	Grasses and broadleaf weeds	5	Inhibitors of photosynthesis at photosystem II Site A

Appendix II Monitoring Data

Water monitoring data for racemic dimethenamid and its transformation products, M23 and M27, are used as surrogate data for dimethenamid-P. The information was found from the PMRA available Canadian water monitoring data and the United States Geological Survey National Water Quality Assessment program for both groundwater and surface water and from the nine year water quality monitoring data, as part of the USEPA Storage and Retrieval (STORET). For both ecoscenario assessment and drinking water assessment, information was sorted into three categories as follows and summarized in (Appendix II Table 1):

1. Residues in known drinking water sources (both surface and groundwater);

2. Residues in ambient water that may serve as a drinking water source (both surface and groundwater); and

3. Residues in ambient water that is unlikely to serve as a drinking water source.

The acute and chronic exposure estimates of dimethenamid and its transformation products are summarized in Appendix II Table 2 for ecoscenario exposure estimate and Appendix II Table 3 for drinking water exposure estimates. The acute exposure value was estimated from monitoring data by determining the 95th percentile of the maximum concentration detected in each monitoring study/site. The chronic exposure value was estimated by determining the 95th percentile of the arithmetic means of all samples at each site (detects and non-detects) from the monitoring studies. The samples with values less than the LOD were given a value of ½ LOD. Groundwater data and data from water distribution systems were not included in the ecoscenario exposure estimate determinations.

Table 1 Summary of Available Monitoring Studies for Dimethenamid and its Transformation Products

Data Source	Location		Minimum Detection or Detection Limit (µg/L)	Number of Systems Tested (or Absolute Number of Samples)	Number of Systems or Samples With Detections	Percentile Detection Frequency	CONCENTRATION (µg/L) (Analysis Includes Only Data With Detections)			Overall Mean Including Non-Detects at ½ LOD (µg/L)
							Mean	95th percentile	Maximum	
Residues in Known and Potential Drinking Water Sources										
Dimethenamid Ethanesulfonic Acid (M27)										
National Water-Quality Assessment Program 2008 (NAWQA) PMRA# 1625189	groundwater (1992-2006)	agricultural land use	0.02-0.05	285	3	1.1	0.138	0.239	0.254	0.02
		other land use	0.02-0.05	384	2	0.52	0.08	-	0.09	0.01
		Mixed land use	0.02-0.05	106	0	-	-	-	-	0.02
		Urban land use	0.02-0.05	7	0	-	-	-	-	0.021
Residues in Ambient Water that May Serve as a Drinking Water Source										
Dimethenamid										
PMRA# 1311110, 1311112	Quebec Yamaska River	2003	0.02	15	12	80	0.09	0.32	0.52	0.07
		2004	0.02	12	10	83.3	0.05	0.10	0.12	0.04
Giroux (1998b) PMRA# 1307581	ruisseau Corbin	1996	0.03	17	4	23.5	0.20	0.46	0.52	0.06
		1997	0.03	34	4	11.8	0.03	0.06	0.06	0.02
	ruisseau David	1996	0.03	6	6	100	0.28	0.68	0.69	0.28
		1997	0.03	6	6	100	0.31	0.75	0.86	0.31
	rivière de l'Achigan	1996	0.03	17	0	-	-	-	-	-
		1997	0.03	29	2	6.9	0.12	0.19	0.20	0.02
	Mouth of Corbin	1997	0.03	6	2	33.3	0.6	0.08	0.08	0.03

Data Source	Location		Minimum Detection or Detection Limit (µg/L)	Number of Systems Tested (or Absolute Number of Samples)	Number of Systems or Samples With Detections	Percentile Detection Frequency	CONCENTRATION (µg/L) (Analysis Includes Only Data With Detections)			Overall Mean Including Non-Detects at ½ LOD (µg/L)
							Mean	95th percentile	Maximum	
Giroux (1999) PMRA# 1307568	rivière Chibouet	1996	0.05	40	27	67.5	0.21	0.73	1.60	0.148
		1997	0.03	37	34	91.9	0.13	0.36	0.40	0.124
		1998	0.03	45	36	80	0.08	0.20	0.28	0.065
	rivière des Hurons	1996	0.05	41	28	68.3	0.13	0.27	1.30	0.094
		1997	0.03	39	31	79.5	0.15	0.50	0.74	0.122
		1998	0.03	51	51	100	0.33	0.99	2.0	0.326
	rivière Saint-Régis	1996	0.05	41	37	90.2	0.59	2.44	7.0	0.538
		1997	0.03	40	40	100	0.59	1.67	4.0	0.588
		1998	0.03	49	33	67.3	0.11	0.39	0.46	0.078
	rivière Saint-Zéphirin	1996	0.05	39	1	2.6	0.05	0.05	0.05	0.026
		1997	0.03	39	11	28.2	0.09	0.27	0.37	0.049
		1998	0.03	48	2	4.2	0.30	0.47	0.49	0.027
	rivière Yamaska	1996	0.05	17	16	94.1	0.20	0.43	0.54	0.188
		1997	0.03	8	8	100	0.44	0.71	0.76	0.440
		1998	0.03	42	33	78.6	0.14	0.50	0.58	0.117
Giroux (2002) PMRA# 1307571	rivière Chibouet	1999	0.03	45	28	62.2	0.09	0.27	0.49	0.06
		2000	0.03	40	13	32.5	0.13	0.37	0.52	0.06
		2001	0.02	46	29	63	0.28	0.90	3.10	0.18
	rivière des Hurons	1999	0.03	45	24	53.3	0.08	0.34	0.49	0.05
		2000	0.03	42	16	38.1	0.14	0.44	0.62	0.08
		2001	0.02	44	27	61.4	0.46	3.06	5.20	0.31
	rivière Saint-Régis	1999	0.03	45	35	77.8	0.18	0.56	1.30	0.15
		2000	0.03	43	43	100	3.95	3.94	130	3.95
		2001	0.02	45	43	95.6	0.37	1.09	1.60	0.36

Data Source	Location		Minimum Detection or Detection Limit (µg/L)	Number of Systems Tested (or Absolute Number of Samples)	Number of Systems or Samples With Detections	Percentile Detection Frequency	CONCENTRATION (µg/L) (Analysis Includes Only Data With Detections)			Overall Mean Including Non-Detects at ½ LOD (µg/L)
							Mean	95th percentile	Maximum	
	rivière Saint-Zéphirin	1999	0.03	46	17	37	0.13	0.35	0.54	0.06
		2000	0.03	43	10	23.3	0.22	0.89	2.20	0.11
		2001	0.02	46	6	13	0.12	0.34	0.41	0.02
	rivière Yamaska	1999	0.03	43	20	46.5	0.10	0.19	0.25	0.05
		2000	0.03	Not Reported	-	-	-	-	-	-
		2001	0.02	46	29	63	0.11	0.29	0.32	0.08
Giroux *et al.* (2006) PMRA# 1398451, 1398452, 1398453	rivière de l'Achigan	2002	0.02	43	31	72.1	0.22	0.98	1.3	0.16
		2003	0.02	41	23	56.1	0.2	0.47	2.7	0.12
		2004	0.02	40	26	65	0.07	0.17	0.23	0.05
	rivière des Hurons	2002	0.02	42	26	61.9	0.15	0.47	1.3	0.09
		2003	0.02	41	21	51.2	0.08	0.18	0.61	0.04
		2004	0.02	41	19	46.3	0.06	0.14	0.17	0.03
	rivière Saint-Régis	2002	0.02	41	41	100	0.33	0.8	4.2	0.33
		2003	0.02	39	37	94.9	0.20	0.69	2.1	0.19
		2004	0.02	39	24	61.5	0.12	0.18	1.4	0.08
	rivière Saint-Zéphirin	2002	0.02	-	-	-	-	-	-	-
		2003	0.02	-	-	-	-	-	-	-
		2004	0.02	39	14	35.9	0.10	0.37	0.39	0.04

Data Source	Location		Minimum Detection or Detection Limit (µg/L)	Number of Systems Tested (or Absolute Number of Samples)	Number of Systems or Samples With Detections	Percentile Detection Frequency	CONCENTRATION (µg/L) (Analysis Includes Only Data With Detections)			Overall Mean Including Non-Detects at ½ LOD (µg/L)
							Mean	95th percentile	Maximum	
USEPA (STORET) PMRA# 1625185	Water Quality Monitoring (1999-2007)	1999	0.02	3	3	100	0.25	0.29	0.29	0.25
		2000	0.02	265	36	13.6	0.31	0.87	1.2	0.05
		2001	0.02	931	105	11.3	0.26	0.86	3.1	0.04
		2002	0.02	1201	125	10.4	0.39	1.58	4.4	0.05
		2003	0.02	1011	55	5.4	0.14	0.46	0.66	0.02
		2004	0.02	1129	59	5.2	0.20	0.54	0.57	0.02
		2005	0.02	1078	51	4.73	0.28	0.92	2	0.02
		2006	0.02	1000	54	5.4	0.26	0.87	2.3	0.02
		2007	0.02	20	0	-	-	-	-	0.01
NAWQA (2008) PMRA# 1625189	United States surface water (1991-2006)	other land use	0.02–0.05	206	17	8.25	0.21	0.67	0.89	0.03
		mixed land use	0.02–0.05	75	7	9.33	0.14	0.36	0.46	0.03
		Agricul-tural land use	0.02–0.05	295	27	9015	0.51	0.98	7	0.06
Dimethenamid Ethanesulfonic Acid (M27)										
NAWQA (2008) PMRA# 1625189	United States surface water (1991-2006)	Urban land use	0.02–0.05	16	-	-	-	-	-	0.03
		other land use	0.02–0.05	362	35	9.67	0.13	0.28	0.36	0.03
		mixed land use	0.02–0.05	313	10	3.19	0.05	0.05	0.15	0.02
		agricultural land use	0.02–0.05	643	66	10.26	0.12	0.25	0.36	0.03

Data Source	Location		Minimum Detection or Detection Limit (µg/L)	Number of Systems Tested (or Absolute Number of Samples)	Number of Systems or Samples With Detections	Percentile Detection Frequency	CONCENTRATION (µg/L) (Analysis Includes Only Data With Detections)			Overall Mean Including Non-Detects at ½ LOD (µg/L)
							Mean	95th percentile	Maximum	
Dimethenamid Oxanilic Acid (M23)										
NAWQA (2008) PMRA# 1625189	United States surface water (1991-2006)	Urban land use	0.02–0.05	16	-	-	-	-	-	0.03
		other land use	0.02–0.05	362	32	8.84	0.15	0.39	0.46	0.03
		mixed land use	0.02–0.05	313	2	0.64	0.10	0.127	0.13	0.02
		agricultural land use	0.02–0.05	643	30	4.67	0.12	0.257	0.35	0.02
Residues in Ambient Water that are Unlikely to Serve as a Drinking Water Source										
Dimethenamid										
Giroux and Therrien (2005) PMRA3# 1311123	station d'épuration de Saint-Hyacinthe	2002	0.02	29	5	17.2	0.03	0.06	0.07	0.02
"—" = not applicable or cannot be calculated based on available data										

Table 2 Concentrations of Dimethenamid and its Transformation Products in Surface Water Estimated from Available Monitoring Data

Chemical	Acute Concentration (µg/L) [1]	Chronic Concentration (µg/L) [2]
Dimethenamid	5.38	0.44
Dimethenamid ethanesulfonic acid (M27)	0.36 [3]	0.03 [4]
Dimethenamid oxanilic acid (M23)	0.46 [3]	0.03 [4]

[1] 95th percentile of the maximum detected concentrations from surface water monitoring studies
[2] 95th percentile of the mean concentration for each study site including ½ LOD for non-detects
[3] maximum concentration detected in surface water in the United States
[4] maximum overall average of detection in surface water in the United States including ½ LOD for non-detects

Table 3 Concentrations of Dimethenamid and Transformation Products in Potential Drinking Water Sources Estimated from Available Monitoring Data

Chemical	Ground Water		Surface Water	
	Acute EEC (µg/L)	Chronic EEC (µg/L)	Acute EEC (µg/L) [1]	Chronic EEC (µg/L) [2]
Dimethenamid	ND	ND	5.47	0.45
Dimethenamid ethanesulfonic acid (M27)	0.25 [3]	0.02 [4]	0.36 [5]	0.03
Dimethenamid oxanilic acid (M23)	ND	ND	0.46 [5]	0.03
Total residue [6]	**0.25**	**0.02**	**6.29**	**0.51**

[1] 95th percentile of the maximum detected concentrations from surface water monitoring studies
[2] 95th percentile of the mean concentration for each study site including ½ LOD for non-detects
[3] maximum concentration detected in groundwater in the United States
[4] maximum arithmetic mean (including ½ LOD) concentration in groundwater in the United States
[5] maximum concentration detected in surface water in the United States
[6] total residue = dimethenamid + dimethenamid ethanesulfonic acid + dimethenamid oxanilic acid

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A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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3.0 Environment

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4.0 Value

ii) Unpublished Information

1.0 Chemistry

2.0 Human and Animal Health

3.0 Environment

4.0 Value